

Designation Run Report

Prevoznik, Thomas - Plaintiffs' Submission

Prevoznik, Thomas 04-17-2019

Prevoznik, Thomas 04-18-2019

Prevoznik, Thomas 05-17-2019

Plaintiff Affirmatives 02:05:49

Defense Completeness Counters 00:02:38

Total Time 02:08:28



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41:21 - 42:04	Prevoznik, Thomas 04-17-2019 (00:00:14) 41:21 Q. As I understand it, you 41:22 currently work for DEA; is that correct? 41:23 A. Yes. 41:24 Q. And what is your position? 42:1 A. I am currently the acting 42:2 section chief of the pharmaceutical 42:3 investigations in the diversion control 42:4 division.	TP01.1
42:11 - 43:18	Prevoznik, Thomas 04-17-2019 (00:01:36) 42:11 And in -- how long have you 42:12 had that position? 42:13 A. I've been acting since 42:14 mid-January of this year. 42:15 Q. How long have you been at 42:16 DEA overall? 42:17 A. Over 28 years. 42:18 Q. And is it fair to say that 42:19 part of the time that you were at DEA, 42:20 you were in the field, one of the field 42:21 offices, or several field offices, and 42:22 part of the time you've been at DEA 42:23 you've been at corporate headquarters? 42:24 A. I've been in the field. 43:1 I've been in our training academy as an 43:2 instructor, and I've also went back to 43:3 the field, and then to headquarters. 43:4 Q. Your current position is at 43:5 headquarters, correct? 43:6 A. Correct. 43:7 Q. And what -- in that 43:8 position, do you have any oversight or 43:9 responsibility related to suspicious 43:10 order monitoring or reporting? 43:11 A. Yes. My -- well, they just 43:12 split our unit, our section to a -- so 43:13 that analytics side, which was ARCOS, 43:14 which includes drug theft loss, and SORs 43:15 data, the output side. They've been 43:16 moved to another section. That was like	TP01.2

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59:07 - 59:19	<p>43:17 two weeks ago. But prior to that it'd 43:18 been under -- under me.</p> <p>Prevoznik, Thomas 04-17-2019 (00:00:28)</p> <p>59:7 Q. Now, prior to your current 59:8 title, which is section chief of 59:9 pharmaceutical investigations, you were 59:10 the unit chief in the same section; is 59:11 that right?</p> <p>59:12 A. No. So in January 2017, I 59:13 got promoted to the associate section 59:14 chief up in pharmaceutical 59:15 investigations.</p> <p>59:16 Prior to that I was the unit 59:17 chief down in our policy and liaison 59:18 section. But I was the unit chief over 59:19 liaison.</p>	TP01.3
59:24 - 60:19	<p>Prevoznik, Thomas 04-17-2019 (00:00:53)</p> <p>59:24 Can you just again describe 60:1 for me at a high level what the purpose 60:2 of the unit is or the primary goals of 60:3 the unit?</p> <p>60:4 A. Well, I mean, what I did was 60:5 I coordinated conferences, whether it was 60:6 the pharmacy diversion awareness 60:7 conferences. I gave a lot of 60:8 presentations. We would have to -- we 60:9 would coordinate with various entities to 60:10 try to get continuing education credits 60:11 for the pharmacists, and the techs. We 60:12 would do the DEA general conference -- 60:13 conferences. You know, the distributor 60:14 conference. We would help our quota unit 60:15 with setting up the manufacturing 60:16 training that they would do.</p> <p>60:17 I mean, we were like the 60:18 spokespeople, as well as coordinating the 60:19 events themselves.</p>	TP01.4
62:07 - 62:17	<p>Prevoznik, Thomas 04-17-2019 (00:00:33)</p> <p>62:7 Q. Let me ask it this way. 62:8 The liaison unit, what</p>	TP01.5

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	62:9 interaction did the liaison unit have 62:10 with suspicious order monitoring or 62:11 reporting? 62:12 A. I mean, at the conferences, 62:13 I mean, I gave presentations in 2013 and 62:14 '15 to the distributor -- at the 62:15 distributor conferences. So, I mean, I 62:16 know I talked about suspicious orders. I 62:17 talked about thresholds.	
63:21 - 64:06	Prevoznik, Thomas 04-17-2019 (00:00:18) 63:21 Q. And did you present at the 63:22 most recent one? 63:23 A. No. I did the '13 and '15. 63:24 Q. You presented at the '13 and 64:1 '15. 64:2 Now, prior to -- as part of 64:3 your preparation, did you come to learn 64:4 of prior distributor conferences that 64:5 took place? 64:6 A. Yes. Mm-hmm.	TP01.6
64:07 - 64:18	Prevoznik, Thomas 04-17-2019 (00:00:28) 64:7 Q. Do you recall just 64:8 approximately what years the other 64:9 distributor conferences were, just 64:10 approximately? 64:11 A. No. The distributor 64:12 conference became more unique around the 64:13 time that we did it. But before that it 64:14 was when they were actually together. It 64:15 was like an industry conference. And 64:16 that was -- that was more frequent, I 64:17 believe. I don't have a time frame for 64:18 you.	TP01.7
71:04 - 71:08	Prevoznik, Thomas 04-17-2019 (00:00:13) 71:4 Unless I say otherwise, when 71:5 I say you, or the DEA, or the 71:6 administration, I'm generally referring 71:7 to the entity that is the Drug 71:8 Enforcement Administration.	TP01.8
84:02 - 84:21	Prevoznik, Thomas 04-17-2019 (00:00:38)	TP01.9

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	84:2 Q. You're always a diversion 84:3 investigator? 84:4 A. Yes, I've been one for 84:5 28 years. 84:6 Q. Okay. Your primary 84:7 responsibilities, you were no longer 84:8 primarily operating as a diversion 84:9 investigator after December 2008, fair? 84:10 A. When I became the 84:11 supervisor? 84:12 Q. Yes. As a supervisor, did 84:13 you continue to function as a diversion 84:14 investigator as a primary part of what 84:15 you were doing? 84:16 A. Not as primary. 84:17 Q. But sometimes as a 84:18 general -- in terms of the supervision of 84:19 investigators, you would provide advice 84:20 and guidance on what they ought to do? 84:21 A. Correct.	
86:16 - 87:02	Prevoznik, Thomas 04-17-2019 (00:00:17)	TP01.10
	86:16 What areas did you train in, 86:17 was it primarily diversion control? 86:18 A. It was all diversion 86:19 control. 86:20 Q. All diversion control? 86:21 A. Yeah, I mean I would assist 86:22 with some of the special agent stuff, 86:23 but... 86:24 Q. How much training do 87:1 diversion investigators as a general 87:2 matter get?	
87:05 - 87:06	Prevoznik, Thomas 04-17-2019 (00:00:03)	TP01.11
	87:5 THE WITNESS: It's 12 weeks. 87:6 The training at Quantico.	
87:08 - 87:11	Prevoznik, Thomas 04-17-2019 (00:00:09)	TP01.12
	87:8 Q. All on diversion control? 87:9 A. Correct. 87:10 Q. And what are the components 87:11 of that training at a high level?	

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87:16 - 88:21	<p>Prevoznik, Thomas 04-17-2019 (00:01:24)</p> <p>87:16 THE WITNESS: So it would be 87:17 the -- the law, we would have law. 87:18 You would have the record 87:19 requirements. It would be 87:20 interviewing. It would be audits. 87:21 Like reviewing records for 87:22 pharmacy audit. Reviewing records 87:23 for distributor audit. Reviewing 87:24 records for a manufacturing audit. 88:1 Ethics training. Just a lot of 88:2 interviewing, practicals. We did 88:3 various practicals as well, just 88:4 to give them like a real life -- 88:5 try to give them a real life 88:6 experience as best we could.</p> <p>88:7 BY MS. MAINIGI:</p> <p>88:8 Q. And after the initial 88:9 12-week training, are there any refresher 88:10 courses that are -- or refresher training 88:11 that is provided to diversion 88:12 investigators?</p> <p>88:13 A. Yes, there is --</p> <p>88:14 Q. How often is that?</p> <p>88:15 A. It depends. Each -- it --</p> <p>88:16 it's typically within three to 88:17 five years.</p> <p>88:18 Q. And how long is the 88:19 refresher training?</p> <p>88:20 A. I believe it was about a 88:21 week.</p>	TP01.13
597:06 - 598:10	<p>Prevoznik, Thomas 04-18-2019 (00:01:11)</p> <p>597:6 Q. Will you state your name, 597:7 rank, and title?</p> <p>597:8 A. Thomas Prevoznik. I am the 597:9 acting section chief of pharmaceutical 597:10 investigations for the DEA's diversion 597:11 control division.</p> <p>597:12 Q. Mr. Prevoznik, my name is 597:13 Paul Farrell, and I am one of the lawyers</p>	TP01.14

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597:14	representing the plaintiffs. And so I	
597:15	thank you for coming here today. And I	
597:16	just wanted to set for the record, we	
597:17	sent a list of subject matters to the	
597:18	United States Drug Enforcement Agency and	
597:19	asked for somebody to be designated to	
597:20	testify on its behalf.	
597:21	You understand that the	
597:22	questions that I ask you today are not in	
597:23	your individual capacity, but we're	
597:24	asking for answers as if it was coming	
598:1	from the DEA itself.	
598:2	A. Correct.	
598:3	Q. So the million-dollar	
598:4	question right out of the gate is, why	
598:5	didn't the DEA do more?	
598:6	So what I want to do is, I	
598:7	have the testimony from the former acting	
598:8	administrator, Robert Patterson. And I'm	
598:9	going to show you a video clip and then	
598:10	ask some follow-up questions. Okay?	
598:12 - 599:06	Prevoznik, Thomas 04-18-2019 (00:00:35)	TP01.15
598:12	THE WITNESS: Okay.	
598:13	MR. FARRELL: 523.	
598:14	BY MR. FARRELL:	
598:15	Q. This is Mr. Patterson's	
598:16	opening statement I believe his testimony	
598:17	before Congress on March 20, 2018, in	
598:18	front of the subcommittee on oversight	
598:19	and investigations, the committee on	
598:20	Energy and Commerce.	
598:21	You're aware that	
598:22	Mr. Patterson testified?	
598:23	A. Yes.	
598:24	Q. And he testified on behalf	
599:1	of the DEA?	
599:2	A. Yes.	
599:3	Q. To Congress under oath?	
599:4	A. Yes.	
599:5	MR. FARRELL: Show the first	

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599:6 clip, please.		
599:7 - 601:20	Prevoznik, Thomas 04-18-2019 (00:02:06)	TP01.16
599:7 (Video clip played as		
599:8 follows:)		
599:9 MR. PATTERSON: Where		
599:10 license revocation is not		
599:11 necessary, we've aggressively		
599:12 pursued civil actions and MOUs		
599:13 designed to ensure compliance.		
599:14 Over the last decade, DEA has		
599:15 levied fines totalling nearly		
599:16 \$390 million against opioid		
599:17 distributors nationwide and		
599:18 entered into MOUs with each.		
599:19 (Video concluded.)		
599:20 BY MR. FARRELL:		
599:21 Q. Mr. Prevoznik, can you		
599:22 verify the accuracy of that statement?		
599:23 A. Yes.		
599:24 Q. So the DEA has in fact		
600:1 attempted to impose civil penalties and		
600:2 conducted investigations into opioid		
600:3 distribution and diversion?		
600:4 A. Correct.		
600:5 Q. I'm going to go to the next		
600:6 clip. This is where the follow-up really		
600:7 begins.		
600:8 (Video clip played as		
600:9 follows:)		
600:10 MR. PATTERSON:		
600:11 Administrative actions, civil		
600:12 fines, and criminal cases are all		
600:13 important steps. Where we have		
600:14 fallen short in the past, it is by		
600:15 not proactively leveraging the		
600:16 data that has been available to		
600:17 us.		
600:18 (Video concluded.)		
600:19 BY MR. FARRELL:		
600:20 Q. Mr. Prevoznik, are you		

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	600:21 familiar with that complaint? 600:22 A. Yes. 600:23 Q. I'm also going to show you 600:24 what has been previously referenced in 601:1 this trial, the jury has heard probably 601:2 several times, is the Energy and 601:3 Commerce's report following the testimony 601:4 of Mr. Patterson as well as the testimony 601:5 from numerous others. 601:6 Are you familiar with this 601:7 report? 601:8 A. Yes, I am. 601:9 Q. And this is on one 601:10 particular page, one of the findings and 601:11 the markings up are the lawyers, not from 601:12 Congress. You'll see where I put the 601:13 Star. And it basically says, "Had 601:14 HDA" -- "Had DEA more proactively used 601:15 ARCOS data, it could have discovered, in 601:16 a period of time at a place called 601:17 Sav-Rite Pharmacy Number 1 that there 601:18 were a lot of pills that were shipped." 601:19 Are you familiar with this 601:20 finding from Congress? 601:22 - 601:22	
	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.17
	601:22 THE WITNESS: Yes. 601:23 - 603:15	TP01.18
	Prevoznik, Thomas 04-18-2019 (00:01:48) 601:23 BY MR. FARRELL: 601:24 Q. So when you and I walk 602:1 through the ARCOS data, what we're 602:2 talking about is this dataset of 602:3 information that you had, correct? 602:4 A. Correct. 602:5 Q. And these are transactions 602:6 between manufacturers and distributors, 602:7 between distributors and pharmacies, that 602:8 are stored in a large database maintained 602:9 by the DEA? 602:10 A. Correct. 602:11 Q. Okay. So what -- what does	

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	<p>602:12 it mean when the DEA's position is that 602:13 you are not proactively using the ARCOS 602:14 data during this time frame? 602:15 A. Well, back during that time 602:16 frame, we were on what we called the 602:17 mainframe. So the process was slower of 602:18 ARCOS data, so when it would be uploaded 602:19 and processed. And so we were months 602:20 behind on getting that data up into the 602:21 system. 602:22 It was -- we were restricted 602:23 to a million transactions of upload per 602:24 night. And we received millions of 603:1 transactions. So that took a while. 603:2 In addition to that, you 603:3 also had, when they uploaded, there would 603:4 be errors, the most typical errors would 603:5 be wrong NDC code, wrong DEA number, or 603:6 the wrong DEA 222 order form number. 603:7 Q. It's my understanding that 603:8 today these transactions are stored 603:9 digitally with the DEA ARCOS database; is 603:10 that correct? 603:11 A. Correct. 603:12 Q. And now we are able to 603:13 presently and retrospectively look back 603:14 and figure out what happened. Is that 603:15 fair? 603:21 - 604:08 Prevoznik, Thomas 04-18-2019 (00:00:28) TP01.19 603:21 THE WITNESS: Yes. 603:22 BY MR. FARRELL: 603:23 Q. Okay. Now, this may be a 603:24 terrible analogy, but my mind, what I'm 604:1 thinking is, just like -- let's say if 604:2 the NSA keeps a log of everybody's cell 604:3 phone calls in the country, they're not 604:4 actively listening to everyone's call, 604:5 but they have the ability to go backwards 604:6 and piece together what happened. Is 604:7 that similar to what the DEA was doing </p>	

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604:11 - 604:11	604:8 with ARCOS? Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.20
604:13 - 604:21	604:11 THE WITNESS: Yes. Prevoznik, Thomas 04-18-2019 (00:00:22) 604:13 Q. Same thing with the SEC. 604:14 There are billions of trades that happen 604:15 on Wall Street, but the SEC isn't 604:16 necessarily the clearinghouse for these 604:17 trades, but it has the capacity to look 604:18 on a computer backwards and figure out 604:19 what happened if somebody broke the law. 604:20 Is that akin to what is going on with the 604:21 DEA and ARCOS during this time frame?	TP01.21
605:01 - 605:24	605:1 THE WITNESS: Yes. 605:2 BY MR. FARRELL: 605:3 Q. So going back and looking 605:4 backwards from this very same energy and 605:5 commerce report, I happened to be 605:6 familiar with it because of the West -- 605:7 because of West Virginia. The Sav-Rite 605:8 Pharmacy from Page 125, Congress went 605:9 back and looked at the old ARCOS data. 605:10 And from it, what it's determined was 605:11 that McKesson Corporation -- are you 605:12 familiar with the company called 605:13 McKesson? 605:14 A. Yes, I am. 605:15 Q. And who are they? 605:16 A. They are a wholesaler, 605:17 distributor. 605:18 Q. McKesson Corporation sold 605:19 five million doses in 2006 and 2007 of 605:20 opium pills to a pharmacy in Kermit, West 605:21 Virginia. Can you, by looking at this 605:22 exhibit, tell me how many people, 605:23 according to Congress, live in Kermit, 605:24 West Virginia?	TP01.22
606:06 - 606:06	606:6 THE WITNESS: 406. Prevoznik, Thomas 04-18-2019 (00:00:02)	TP01.23

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607:01 - 607:05	Prevoznik, Thomas 04-18-2019 (00:00:14) 607:1 Q. Is there any basis 607:2 that you can make up in reality or 607:3 otherwise where a town of 400 people have 607:4 a medical need for five million pills of 607:5 opium in a span of 24 months?	TP01.24
607:09 - 607:13	Prevoznik, Thomas 04-18-2019 (00:00:05) 607:9 THE WITNESS: Correct. 607:10 There isn't. There isn't. 607:11 BY MR. FARRELL: 607:12 Q. There is absolutely no way, 607:13 is there?	TP01.25
607:16 - 607:16	Prevoznik, Thomas 04-18-2019 (00:00:01) 607:16 THE WITNESS: No.	TP01.26
609:14 - 610:17	Prevoznik, Thomas 04-18-2019 (00:01:01) 609:14 Q. Beyond the opening statement 609:15 from the DEA to Congress through 609:16 Mr. Patterson here, there were also 609:17 questions and answers. 609:18 So one of the questions 609:19 Congress asked the DEA was: Why did the 609:20 DEA communications with industry fail to 609:21 prevent the kinds of major breakdowns 609:22 apparent in West Virginia? 609:23 I'm going to play for you 609:24 Mr. Patterson's response. 610:1 (Video clip played as 610:2 follows:) 610:3 ROBERT PATTERSON: I think 610:4 when you go back to that time 610:5 frame on the suspicious orders 610:6 reports, there was two major 610:7 failures. One was either a lack 610:8 of information contained therein, 610:9 or not filing them in -- in this 610:10 instance that they had. I think 610:11 that started the problem, quite 610:12 frankly, and a lot of the 610:13 frustration came from chasing down 610:14 the registrants and ultimately	TP01.27

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612:20 - 613:03	<p>610:15 reminding them of their 610:16 responsibility in this regulated 610:17 area.</p> <p>Prevoznik, Thomas 04-18-2019 (00:00:15)</p> <p>612:20 Q. Okay. Back on -- back on 612:21 the questions. 612:22 My question to you is, who 612:23 is the DEA referencing when they are 612:24 talking about chasing down registrants. 613:1 Are we talking about the 613:2 wholesale distributors? 613:3 A. Yes.</p>	TP01.28
613:07 - 613:14	<p>Prevoznik, Thomas 04-18-2019 (00:00:14)</p> <p>613:7 Q. And then it says that the 613:8 DEA was -- part of their frustration was 613:9 having to chase down the registrants and 613:10 remind them of their responsibilities. 613:11 Can you explain what that 613:12 means? 613:13 What does the DEA mean when 613:14 it says this to Congress?</p>	TP01.29
613:17 - 613:24	<p>Prevoznik, Thomas 04-18-2019 (00:00:20)</p> <p>613:17 THE WITNESS: It means that 613:18 we, with our letters in 2006, we 613:19 were reiterating what their 613:20 responsibility was to report 613:21 suspicious orders. They may 613:22 needed to -- that the registrants 613:23 needed to meet effective controls 613:24 to guard against diversion.</p>	TP01.30
615:01 - 615:05	<p>Prevoznik, Thomas 04-18-2019 (00:00:14)</p> <p>615:1 Q. Was it the DEA's assessment 615:2 during the time frame of 2006 and 2007 615:3 that the wholesale distributors, as an 615:4 industry, were not complying with their 615:5 regulatory duties?</p>	TP01.31
615:08 - 616:14	<p>Prevoznik, Thomas 04-18-2019 (00:01:01)</p> <p>615:8 THE WITNESS: Correct. 615:9 BY MR. FARRELL: 615:10 Q. Now, we're going to go to</p>	TP01.32

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	<p>615:11 the next clip. 615:12 The follow-up with the DEA 615:13 is that a congressman asked the DEA about 615:14 the settlements with industry in the 615:15 past. And asked them why the past 615:16 settlements were not effective in 615:17 achieving compliance. 615:18 Here is Mr. Patterson's 615:19 response on behalf of the DEA. 615:20 (Video clip played as 615:21 follows:) 615:22 ROBERT PATTERSON: And 615:23 again, this goes back to the 615:24 frustration of the day. And I 616:1 know that the -- the folks that 616:2 were in diversion back in 2010 and 616:3 2012 struggled with the fact that 616:4 these MOU or MOAs had been put in 616:5 place with these companies and 616:6 they blatantly violated them 616:7 again. 616:8 (Video concluded.) 616:9 BY MR. FARRELL: 616:10 Q. So my question to you is, is 616:11 what can the DEA do if the civil 616:12 penalties that they are imposing are not 616:13 prohibitive or do not cause the wholesale 616:14 distributors to change their conduct?</p>	TP01.33
616:19 - 617:04	<p>Prevoznik, Thomas 04-18-2019 (00:00:21)</p> <p>616:19 THE WITNESS: Okay. We 616:20 could take -- we could file an 616:21 order to show cause on them. If 616:22 we could show imminent danger to 616:23 the public, we could file an ISO 616:24 against them. We could perhaps 617:1 take other civil action or an 617:2 injunctive action against the 617:3 company, or we could criminally 617:4 prosecute.</p>	TP01.34

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	621:5 So the last question that 621:6 was pending and answered, I asked: "Was 621:7 the DEA in fact frustrated that 621:8 registrants were blatantly violating the 621:9 MOUs from prior administrative actions?" 621:10 And your answer was: "Yes." 621:11 There were appropriate 621:12 objections that were made that will be 621:13 resolved one day in the future. So 621:14 here's where my follow-up questions 621:15 comes. 621:16 A. Okay. 621:17 Q. Does that include Cardinal 621:18 Health's 2008 MOU and settlement which 621:19 resulted in a second DEA fine? 621:20 A. Yes.	
624:13 - 624:15	Prevoznik, Thomas 04-18-2019 (00:00:08)	TP01.35
	624:13 Q. Does that include McKesson's 624:14 2008 MOU and settlement which resulted in 624:15 a second DEA fine?	
624:18 - 624:18	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.36
	624:18 THE WITNESS: Yes.	
625:02 - 625:05	Prevoznik, Thomas 04-18-2019 (00:00:13)	TP01.37
	625:2 Q. Acting Administrator Robert 625:3 Patterson testified that the DEA has 625:4 1,500 people to monitor 1.73 million 625:5 registrants. Is that an accurate number?	
625:08 - 625:08	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.38
	625:8 THE WITNESS: Yes.	
628:12 - 629:07	Prevoznik, Thomas 04-18-2019 (00:00:59)	TP01.39
	628:12 Q. So specifically what 628:13 I'm referencing is Cardinal Health's 628:14 reply brief, in Cardinal Health versus 628:15 Eric Holder, which was a preliminary 628:16 injunction filed by Cardinal Health in a 628:17 DC District Court. And in it -- in the 628:18 reply brief there's a provision in here 628:19 that I read to you. And in essence what 628:20 it says is that if you get a suspicious 628:21 order, and you block it, that Cardinal	

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	<p>628:22 Health would terminate that customer and 628:23 not sell to it anymore. 628:24 Do you agree that if a 629:1 wholesale distributor gets a flag of a 629:2 suspicious order, that they've determined 629:3 to be a suspicious order, and that they 629:4 block that shipment, that they should 629:5 terminate all future sales to that same 629:6 customer until they can rule out that 629:7 diversion is occurring?</p> <p>629:14 - 630:13 Prevoznik, Thomas 04-18-2019 (00:01:14)</p> <p>629:14 THE WITNESS: Yes, I would 629:15 agree. 629:16 BY MR. FARRELL: 629:17 Q. The same thing applies to a 629:18 document involving McKesson. 629:19 On August 13, 2014, the 629:20 United States Department of Justice was 629:21 communicating with the lawyer for 629:22 McKesson which ended up resulting in a 629:23 \$150 million fine. 629:24 And in this discussion, the 630:1 DEA notes, and I'm reading from Bates 630:2 Stamp MCKMDL 00409224, that the McKesson 630:3 operations manual says the following 630:4 quote: 630:5 "Once McKesson deems an 630:6 order and/or a customer suspicious, 630:7 McKesson is required to act. This means 630:8 all controlled substance sales to that 630:9 customer must cease and the DEA must be 630:10 notified." 630:11 Does the DEA agree with 630:12 those duties? 630:13 A. Yes.</p> <p>632:05 - 632:14 Prevoznik, Thomas 04-18-2019 (00:00:23)</p> <p>632:5 Q. So, cleaning up a couple of 632:6 other things. 632:7 There was some testimony 632:8 yesterday, or today actually, from my</p>	TP01.40
		TP01.41

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	632:9 learned colleague, that 1.2 million 632:10 suspicious orders were reported to the 632:11 DEA between 2007 and 2018. 632:12 Do you recall that 632:13 testimony? 632:14 A. Yes.	
632:17 - 632:19	Prevoznik, Thomas 04-18-2019 (00:00:05)	TP01.42
	632:17 Q. If those suspicious orders 632:18 were filled, is that a, per se, violation 632:19 of federal law?	
632:22 - 632:22	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.43
	632:22 THE WITNESS: Yes.	
633:04 - 633:08	Prevoznik, Thomas 04-18-2019 (00:00:11)	TP01.44
	633:4 Q. The foundation of our 633:5 democracy arises out of the U.S. code. 633:6 So I'm going to ask a couple of general 633:7 questions about some code provisions that 633:8 I'm sure you're very familiar with.	
633:12 - 633:14	Prevoznik, Thomas 04-18-2019 (00:00:09)	TP01.45
	633:12 Q. The first one is the statute 633:13 of United States Code Section 801. And I 633:14 ask for it to be shown on the screen.	
633:15 - 634:01	Prevoznik, Thomas 04-18-2019 (00:00:26)	TP01.46
	633:15 So you've been asked in the 633:16 past, with the focus on Subparagraph 1, 633:17 that many of the controlled substances 633:18 that are distributed in America, 633:19 prescribed and dispensed, have a useful 633:20 and legitimate medical purpose and that 633:21 they are necessary to maintain the health 633:22 and general welfare of the American 633:23 people. 633:24 That's a true statement, is 634:1 it not?	
634:09 - 634:12	Prevoznik, Thomas 04-18-2019 (00:00:07)	TP01.47
	634:9 Q. So we're going to skip down 634:10 to the part they omitted, which is 634:11 Subparagraph 2, and I'd ask for you to 634:12 read that into the record.	
634:14 - 635:01	Prevoznik, Thomas 04-18-2019 (00:00:20)	TP01.48

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	634:14 THE WITNESS: "The illegal 634:15 importation, manufacture, 634:16 distribution and possession and 634:17 improper use of controlled 634:18 substances have a substantial and 634:19 detrimental effect on the health 634:20 and general welfare of the 634:21 American people." 634:22 BY MR. FARRELL: 634:23 Q. Is this consistent with the 634:24 guidance provided by the DEA to 635:1 registrants?	
635:04 - 635:04	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.49
	635:4 THE WITNESS: Yes.	
636:22 - 637:12	Prevoznik, Thomas 04-18-2019 (00:00:39) 636:22 Q. Go to the next slide. And 636:23 this is the United States Code Section, 636:24 which has a registration requirement. 637:1 And it includes a duty imposed upon the 637:2 registrants to comply with Paragraph 1. 637:3 Will you please read that into the 637:4 record? 637:5 A. "Maintenance of effective 637:6 control against diversion of particular 637:7 controlled substances into other than 637:8 legitimate medical, scientific, and 637:9 industrial channels." 637:10 Q. And is this consistent with 637:11 the guidance provided by the DEA to 637:12 registrants?	TP01.50
637:15 - 637:15	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.51
	637:15 THE WITNESS: Yes. Yes.	
638:10 - 638:20	Prevoznik, Thomas 04-18-2019 (00:00:28) 638:10 Q. Title II, Control 638:11 Enforcement, states, "This bill provides 638:12 for control by the Justice Department of 638:13 problems related to drug abuse through 638:14 registration of manufacturers, 638:15 wholesalers, retailers, and all others in 638:16 the legitimate distribution chain, and	TP01.52

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638:24 - 638:24	638:17 makes transactions outside the legitimate 638:18 distribution chain illegal." 638:19 Is this consistent with the 638:20 guidance the DEA provided to registrants? Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.53
639:02 - 639:07	638:24 THE WITNESS: Yes. Prevoznik, Thomas 04-18-2019 (00:00:20) 639:2 Q. If you violate Section 823, 639:3 or the provisions, the regulations 639:4 enacted by the DEA related to the 639:5 distribution of controlled substances, 639:6 those acts are illegal. Agreed or 639:7 disagree?	TP01.54
639:10 - 639:10	Prevoznik, Thomas 04-18-2019 (00:00:01) 639:10 THE WITNESS: Agreed.	TP01.55
639:22 - 640:17	Prevoznik, Thomas 04-18-2019 (00:00:42) 639:22 Q. The quote from the 639:23 congressional record is, "The bill is 639:24 designed to improve the administration 640:1 and regulation by the manufacturer" -- 640:2 "by the manufacturing, distribution and 640:3 dispensing of controlled substances by 640:4 providing a quote-unquote closed system 640:5 of drug distribution for legitimate 640:6 handlers of such drugs. 640:7 "Such a closed system should 640:8 significantly reduce the widespread 640:9 diversion of these drugs out of 640:10 legitimate channels into the illicit 640:11 market, while at the same time providing 640:12 the legitimate drug industry with a 640:13 unified approach to narcotic and 640:14 dangerous drug control." 640:15 Is this consistent with the 640:16 guidance provided by the DEA to 640:17 registrants?	TP01.56
640:20 - 640:20	Prevoznik, Thomas 04-18-2019 (00:00:01) 640:20 THE WITNESS: Yes.	TP01.57
641:14 - 641:18	Prevoznik, Thomas 04-18-2019 (00:00:13) 641:14 Does the DEA take the	TP01.58

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	641:15 position that the purpose of the 641:16 Controlled Substances Act and its federal 641:17 regulations is to prevent diversion? 641:18 A. Yes.	
642:03 - 642:05	Prevoznik, Thomas 04-18-2019 (00:00:08)	TP01.59
	642:3 Q. Does the DEA agree that 642:4 diversion is foreseeable if registrants 642:5 fail to comply with federal law?	
642:10 - 642:14	Prevoznik, Thomas 04-18-2019 (00:00:09)	TP01.60
	642:10 THE WITNESS: Correct. 642:11 BY MR. FARRELL: 642:12 Q. And failure to comply 642:13 enables more diversion. Does the DEA 642:14 agree with that?	
643:01 - 643:05	Prevoznik, Thomas 04-18-2019 (00:00:10)	TP01.61
	643:1 THE WITNESS: Yes. 643:2 BY MR. FARRELL: 643:3 Q. Does the DEA believe that 643:4 more diversion is detrimental to public 643:5 health and safety?	
643:08 - 643:12	Prevoznik, Thomas 04-18-2019 (00:00:13)	TP01.62
	643:8 THE WITNESS: Yes. 643:9 BY MR. FARRELL: 643:10 Q. Does the DEA agree that the 643:11 more pills which unlawfully enter the 643:12 market results in more diversion?	
643:15 - 643:15	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.63
	643:15 THE WITNESS: Yes.	
643:16 - 643:17	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.64
	643:16 MR. FARRELL: Go to the next 643:17 slide.	
643:19 - 643:23	Prevoznik, Thomas 04-18-2019 (00:00:11)	TP01.65
	643:19 Q. This is a provision about 643:20 penalties. Does the DEA agree that the 643:21 price for participation in illegal 643:22 traffic of controlled substances should 643:23 be prohibitive?	
644:11 - 644:11	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.66
	644:11 THE WITNESS: Yes.	
644:11 - 644:16	Prevoznik, Thomas 04-18-2019 (00:00:10)	TP01.67

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	<p>644:11 THE WITNESS: Yes.</p> <p>644:12 BY MR. FARRELL:</p> <p>644:13 Q. Is this one of the reasons</p> <p>644:14 that the DEA has escalated the amount of</p> <p>644:15 fines that it has levied against</p> <p>644:16 registrants that are repeated violators?</p>	
644:22 - 644:22	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.68
	<p>644:22 THE WITNESS: Yes.</p>	
661:19 - 663:09	Prevoznik, Thomas 04-18-2019 (00:01:52)	TP01.69
	<p>661:19 Q. All right. The next</p> <p>661:20 document that I'm going to show you comes</p> <p>661:21 from discovery in this case. And it's</p> <p>661:22 the NWDA suspicious order monitoring</p> <p>661:23 system.</p> <p>661:24 And I believe that the</p> <p>662:1 government has it included in its folder,</p> <p>662:2 its materials file.</p> <p>662:3 Have you seen this document</p> <p>662:4 before?</p> <p>662:5 A. Can I see more than that?</p> <p>662:6 Q. I think it's under -- it's</p> <p>662:7 in one --</p> <p>662:8 A. In my tabs, my folder?</p> <p>662:9 Q. Yeah.</p> <p>662:10 A. Yes.</p> <p>662:11 Q. I'll give you a second if</p> <p>662:12 you want to flip through it.</p> <p>662:13 A. That's all I see.</p> <p>662:14 I'm familiar with this.</p> <p>662:15 Q. This is a document that was</p> <p>662:16 in the files of Cardinal Health. And</p> <p>662:17 it's stamped as received in 1993, but</p> <p>662:18 I'll represent to you that it contains</p> <p>662:19 some older 1984 references later on.</p> <p>662:20 I'm going just to ask you a</p> <p>662:21 few basic questions about it. And I'll</p> <p>662:22 represent to you that the NWDA is a trade</p> <p>662:23 group for the wholesale distributors at</p> <p>662:24 some point in time.</p> <p>663:1 Go to Page 3.</p>	

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	663:2 MR. FARRELL: Take that down 663:3 first if you don't mind. I'm 663:4 sorry. I was talking to John. 663:5 Take out the blowup. 663:6 Go ahead. Put it back up. 663:7 BY MR. FARRELL: 663:8 Q. So this is something very 663:9 specific that I want to ask the DEA.	
665:14 - 665:18	Prevoznik, Thomas 04-18-2019 (00:00:17)	TP01.70
	665:14 Q. Go all the way to Page 7. 665:15 In the middle of the page in Paragraph 9, 665:16 "Single suspicious orders." For purposes 665:17 of context I'd like you to read this 665:18 aloud.	
665:21 - 666:12	Prevoznik, Thomas 04-18-2019 (00:00:28)	TP01.71
	665:21 THE WITNESS: "Single orders 665:22 of unusual size or deviation must 665:23 be reported immediately. The 665:24 submission of a monthly printout 666:1 of after-the-fact sales will not 666:2 relieve a registrant from the 666:3 responsibility of reporting these 666:4 single excessive or suspicious 666:5 orders. 666:6 "DEA has interpreted orders 666:7 to mean prior to shipment." 666:8 BY MR. FARRELL: 666:9 Q. Is this statement consistent 666:10 with the guidance provided by the DEA to 666:11 registrants? 666:12 A. Yes.	
666:22 - 667:02	Prevoznik, Thomas 04-18-2019 (00:00:10)	TP01.72
	666:22 Q. I'm not asking you to 666:23 speculate. As a matter of fact, is this 666:24 consistent with what the DEA has told its 667:1 registrants is required to comply with 667:2 federal law?	
667:10 - 667:10	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.73
	667:10 THE WITNESS: Yes.	
667:23 - 668:07	Prevoznik, Thomas 04-18-2019 (00:00:21)	TP01.74

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	667:23 The next thing I'm going to 667:24 do is I'm going to show you from Page 8, 668:1 attached to this in the Cardinal Health 668:2 files, is a cover sheet that says letters 668:3 from DEA approving the format. 668:4 And if you look, the first 668:5 letter is dated April 27, 1984. 668:6 Are you familiar with this 668:7 correspondence?	
668:22 - 668:24	Prevoznik, Thomas 04-18-2019 (00:00:03)	TP01.75
	668:22 Q. Are you familiar with this 668:23 document? 668:24 A. No.	
669:09 - 669:15	Prevoznik, Thomas 04-18-2019 (00:00:16)	TP01.76
	669:9 Q. Okay. So what I'm going to 669:10 ask you is, is to flip to Page 2 and see 669:11 Mr. Thomas Gitchell, acting chief 669:12 diversion of operations section. Are you 669:13 familiar with Mr. Gitchell? 669:14 A. Yes, I know who he -- I know 669:15 who he is.	
671:04 - 671:07	Prevoznik, Thomas 04-18-2019 (00:00:10)	TP01.77
	671:4 Q. The date is April 27, 1984. 671:5 You'll see in the bottom right-hand 671:6 corner this is a document that is in the 671:7 Cardinal Health files.	
671:11 - 672:04	Prevoznik, Thomas 04-18-2019 (00:00:46)	TP01.78
	671:11 Q. And so I'm going to ask that 671:12 the -- that the main paragraph be blown 671:13 up so we can read it. 671:14 So the NWDA policy that 671:15 was -- that we just walked through, is 671:16 what this reference is to. 671:17 And I'd ask for you to read 671:18 it, the portion that's highlighted. 671:19 A. "The NWDA's draft format for 671:20 a suspicious order" -- "order monitoring 671:21 system provides an excellent framework 671:22 for distributor registrants to design and 671:23 operate a system to disclose to the	

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	671:24 registrant suspicious orders of 672:1 controlled substances."	
	672:2 Q. Very good.	
	672:3 Now I'd like you to read the	
	672:4 next sentence.	
672:07 - 672:18	Prevoznik, Thomas 04-18-2019 (00:00:21)	TP01.79
	672:7 THE WITNESS: "However, I am	
	672:8 compelled to note, as I have in	
	672:9 our previous discussions, that any	
	672:10 automated data processing system	
	672:11 may provide the means and	
	672:12 mechanism for compliance when the	
	672:13 data is carefully reviewed and	
	672:14 monitored by the wholesaler."	
	672:15 BY MR. FARRELL:	
	672:16 Q. Is this statement consistent	
	672:17 with guidance provided by the DEA to	
	672:18 registrants?	
673:02 - 673:16	Prevoznik, Thomas 04-18-2019 (00:00:28)	TP01.80
	673:2 THE WITNESS: Yes.	
	673:3 BY MR. FARRELL:	
	673:4 Q. Now, go to the final	
	673:5 sentence. Will you please read this	
	673:6 aloud?	
	673:7 A. "As previously discussed, an	
	673:8 after-the-fact computer printout of sales	
	673:9 data does not relieve a registrant of its	
	673:10 responsibility to report excessive or	
	673:11 suspicious orders when discovered. I am	
	673:12 enclosing a copy of your draft with my	
	673:13 pen and ink changes."	
	673:14 Q. Is this consistent with the	
	673:15 guidance provided by the DEA to	
	673:16 registrants?	
673:19 - 673:19	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.81
	673:19 THE WITNESS: Yes.	
674:08 - 674:13	Prevoznik, Thomas 04-18-2019 (00:00:17)	TP01.82
	674:8 Q. Has after the fact reporting	
	674:9 of suspicious orders ever been in	
	674:10 compliance with federal law according to	

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	674:11 the DEA's guidance provided to 674:12 registrants? 674:13 A. No.	
675:03 - 675:07	Prevoznik, Thomas 04-18-2019 (00:00:16) 675:3 Q. So from the Cardinal Health 675:4 files comes a second letter from the DEA. 675:5 And it's dated approximately three weeks 675:6 later, May 16, 1984. And it's again from 675:7 the DEA.	TP01.83
679:18 - 680:05	Prevoznik, Thomas 04-18-2019 (00:00:26) 679:18 Q. Would you please read the 679:19 highlighted section. 679:20 A. "However, I want to make it 679:21 clear that the submission of a monthly 679:22 printout of after-the-fact sales will not 679:23 relieve a registrant from the 679:24 responsibility of reporting excessive or 680:1 suspicious orders. DEA has interpreted 680:2 orders to mean prior to shipment." 680:3 Q. Is this statement consistent 680:4 with the guidance the DEA has always 680:5 provided to registrants?	TP01.84
680:08 - 680:08	Prevoznik, Thomas 04-18-2019 (00:00:01) 680:8 THE WITNESS: Yes.	TP01.85
692:10 - 692:18	Prevoznik, Thomas 04-18-2019 (00:00:20) 692:10 Q. Mr. Prevoznik, the next 692:11 document I'm going to reference is 692:12 actually in your notebook. 692:13 A. Okay. 692:14 Q. In the reliance materials 692:15 that you disclosed yesterday. 692:16 And it's the -- from the 692:17 1996 diversion investigators manual. 692:18 Section 5126.	TP01.86
693:01 - 694:13	Prevoznik, Thomas 04-18-2019 (00:01:32) 693:1 Q. On behalf of the DEA, do you 693:2 recognize this document? 693:3 A. Yes, I do. 693:4 Q. What is it? 693:5 A. It is part of our diversion	TP01.87

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693:6 investigators manual. 693:7 Q. What does that mean? 693:8 What -- what is a diversion 693:9 investigators manual? 693:10 A. It's a manual that breaks 693:11 down our responsibilities, our job. 693:12 It -- it covers the whole gambit of what 693:13 registration is -- what a registrant is, 693:14 down to record reports, requirements. It 693:15 goes through our scheduled 693:16 investigations, pre-registration 693:17 investigations, how to -- conducting 693:18 audits when we do the scheduled 693:19 investigation, what topics, what areas to 693:20 cover. 693:21 It covers controlled 693:22 substances -- controlled substances. It 693:23 also covers the chemicals, List I 693:24 chemicals, the requirements of that, as 694:1 well as preregistration investigations of 694:2 chemicals, applicants. 694:3 It covers the -- the gambit 694:4 of exactly what our job is. 694:5 Q. Are these -- in this page 694:6 that we're showing here, the bottom 694:7 right-hand corner is a Bates stamp. Can 694:8 you read that Bates stamp? 694:9 A. 00025231. 694:10 Q. Okay. Is this a document 694:11 produced by the DEA in this litigation at 694:12 the request of counsel for the diversion 694:13 investigators manual from 1996? 694:15 - 695:15 Prevoznik, Thomas 04-18-2019 (00:00:46)	TP01.88	
694:15 We'll stipulate that we 694:16 produced it. 694:17 MR. FARRELL: Thank you. 694:18 BY MR. FARRELL: 694:19 Q. So the title of Section 5126 694:20 says what? 694:21 A. Requirement to report		

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694:22 suspicious orders. 694:23 Q. Would you read the first 694:24 sentence of the first paragraph aloud? 695:1 A. "Registrants are required to 695:2 inform DEA of suspicious orders in 695:3 accordance with 21 C.F.R. 1301.74(b). 695:4 DEA field offices are not to approve or 695:5 disapprove supplier shipments of 695:6 controlled substances. The 695:7 responsibility for making the decision to 695:8 ship rests with the supplier. No (sic) 695:9 exception to this occurs when a supplier 695:10 complies with a DEA field office's 695:11 request to initiate a controlled delivery 695:12 of controlled substances." 695:13 Q. Is this consistent with the 695:14 guidance provided by the DEA to 695:15 registrants? 695:17 - 696:10	Prevoznik, Thomas 04-18-2019 (00:00:36)	TP01.89
695:17 THE WITNESS: Yes. 695:18 MR. FARRELL: Now, if you'll 695:19 go down to -- keep going. 695:20 BY MR. FARRELL: 695:21 Q. Beginning with 695:22 "registrants," could you begin reading, 695:23 please. 695:24 A. "Registrants who routinely 696:1 report suspicious orders, yet fill these 696:2 orders, with reason to believe they are 696:3 destined for the illicit market, are 696:4 expressing an attitude of 696:5 irresponsibility that is detriment to the 696:6 public health and safety as set forth in 696:7 21 U.S.C. 823 and 824." 696:8 Q. Thank you. Is this 696:9 consistent with the guidance provided by 696:10 the DEA to registrants? 696:15 - 696:24	Prevoznik, Thomas 04-18-2019 (00:00:23)	TP01.90

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696:17 - 696:24	Q. So this is the official policy of the DEA as of 1996, agreed? A. Yes.	
696:25 - 696:29	Q. Is this the position that the DEA was instructing its diversion	
696:30 - 696:34	investigators to take when looking into cases involving the distribution of controlled substances?	
697:06 - 697:10	Prevoznik, Thomas 04-18-2019 (00:00:12)	TP01.91
697:11 - 697:15	Q. In 1996. A. Yes.	
697:16 - 697:37	Q. Are you aware of any deviation or change from that position by the DEA since 1996?	
697:38 - 698:09	Prevoznik, Thomas 04-18-2019 (00:00:43)	TP01.92
698:10 - 698:21	THE WITNESS: No.	
698:22 - 698:24	BY MR. FARRELL:	
698:25 - 698:37	Q. So the next sentence is just a recitation of the suspicious order definition. What I'd like you to do is go down to where it starts, "The supplier can determine," and begin reading aloud.	
698:38 - 698:49	A. "The supplier can determine whether the order is excessive by checking their own sales and establishing the average amount of controlled substances shipped to registrants of the same apparent size in a particular geographic area."	
698:50 - 698:54	Q. Read the next sentence,	
698:55 - 698:57	please.	
698:58 - 698:66	A. "If the customer exceeds this threshold, the request should be viewed as suspicious."	
698:67 - 698:71	Q. Is this consistent with the	
698:72 - 698:76	guidance that the DEA provided to	
698:77 - 698:79	registrants since at least 1996?	
698:80 - 698:84	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.93
698:85 - 698:87	THE WITNESS: Yes.	
700:04 - 700:09	Prevoznik, Thomas 04-18-2019 (00:00:17)	TP01.94

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	700:4 Q. So if you take an average of 700:5 the registrants in the area and you 700:6 calculate that, if a customer exceeds 700:7 that average, is that a red flag for a 700:8 wholesale distributor that the order may 700:9 be suspicious?	
700:13 - 700:13	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.95
	700:13 THE WITNESS: Yes.	
700:15 - 700:17	Prevoznik, Thomas 04-18-2019 (00:00:09)	TP01.96
	700:15 Q. And is that consistent with 700:16 the directives the DEA has given to 700:17 registrants since at least 1996?	
700:20 - 700:24	Prevoznik, Thomas 04-18-2019 (00:00:09)	TP01.97
	700:20 THE WITNESS: Yes.	
	700:21 BY MR. FARRELL:	
	700:22 Q. The next sentence, would you 700:23 read, please.	
	700:24 A. I forgot where I stopped.	
701:02 - 701:11	Prevoznik, Thomas 04-18-2019 (00:00:22)	TP01.98
	701:2 A. "This activity, over 701:3 extended periods of time, would lead a 701:4 reasonable person to believe that 701:5 controlled substances possibly are being 701:6 diverted.	
	701:7 Q. Now, so what I'm asking you 701:8 is, when you read this, is it fair to 701:9 assume that this is consistent with the 701:10 DEA's guidance to industry since at least 701:11 1996?	
701:16 - 702:08	Prevoznik, Thomas 04-18-2019 (00:00:38)	TP01.99
	701:16 THE WITNESS: Yes.	
	701:17 BY MR. FARRELL:	
	701:18 Q. Would you read the next 701:19 sentence, please.	
	701:20 A. "An investigation will be 701:21 conducted for possible violation of the 701:22 CSA and regulations upon determining that 701:23 the reporting registrant, as a general 701:24 practice, does not voluntarily halt 702:1 shipments of controlled substances to	

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	702:2 registrants involved in suspected 702:3 diversion or to registrants against whom 702:4 previous action has been taken." 702:5 Q. Is this consistent with the 702:6 guidance provided by the DEA to 702:7 registrants since at least 1996? 702:8 A. Yes.	
702:24 - 703:08	Prevoznik, Thomas 04-18-2019 (00:00:26)	TP01.100
	702:24 Based upon this 1996 703:1 document, was it the DEA's position that 703:2 a registrant should halt shipments of 703:3 controlled substances that are involved 703:4 in suspected diversion? 703:5 A. Yes. 703:6 Q. And does that include when a 703:7 registrant has placed orders repeatedly 703:8 in excess of the regional average?	
703:13 - 703:13	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.101
	703:13 THE WITNESS: Yes.	
709:02 - 709:06	Prevoznik, Thomas 04-18-2019 (00:00:14)	TP01.102
	709:2 Q. Is it fair to reach the 709:3 conclusion that the DEA disclosed to 709:4 Cardinal Health in the year 2003 709:5 Section 5126 of the 1996 diversion 709:6 investigators manual?	
709:10 - 709:10	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.103
	709:10 THE WITNESS: Yes.	
710:12 - 711:08	Prevoznik, Thomas 04-18-2019 (00:00:41)	TP01.104
	710:12 Q. Mr. Prevoznik, do you 710:13 recognize this document? 710:14 A. Yes. 710:15 Q. What is it? 710:16 A. It's a report to the U.S. 710:17 attorneys -- Attorney General. It's a 710:18 report by the suspicious orders task 710:19 force that was mandated to convene, and 710:20 it's their report based on the 710:21 Comprehensive Methamphetamine Control Act 710:22 in 1996. 710:23 Q. To the best of your	

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	<p>710:24 knowledge, is this a true and accurate 711:1 copy of the report provided by the United 711:2 States Drug Enforcement Administration to 711:3 Attorney General Janet Reno? 711:4 A. To the best of my knowledge, 711:5 yes. 711:6 Q. What is the date of the 711:7 document? 711:8 A. October 1998.</p>	
712:07 - 712:17	<p>Prevoznik, Thomas 04-18-2019 (00:00:23)</p> <p>712:7 Q. Can you tell me in general, 712:8 do you -- does the DEA have an 712:9 understanding of what the purpose was of 712:10 this report that it generated for the 712:11 Attorney General? 712:12 A. It is our understanding that 712:13 this report was to discuss how to put a 712:14 suspicious ordering system forward to 712:15 handle the listed chemicals because of 712:16 the methamphetamine problem that we were 712:17 having in the United States.</p>	TP01.105
712:18 - 713:04	<p>Prevoznik, Thomas 04-18-2019 (00:00:32)</p> <p>712:18 Q. Now, this is also from the 712:19 executive summary. And it says that "the 712:20 charter required the establishment of a 712:21 task force to prepare recommendations 712:22 concerning additional guidelines to be 712:23 used by the chemical industry in 712:24 complying with 21 U.S.C. 830(b)(1)(A)." "The 713:1 Did I read that accurately? 713:2 A. Yes. 713:3 Q. Are you familiar with 713:4 21 U.S.C. 830(b)(1)(A)?</p>	TP01.106
713:20 - 714:01	<p>Prevoznik, Thomas 04-18-2019 (00:00:24)</p> <p>713:20 This provision that we're 713:21 looking at, and the distinction that I 713:22 want to make, what is the DEA's 713:23 understanding of the types of 713:24 transactions that should be reported as 714:1 suspicious pursuant to 21 U.S.C. 830?</p>	TP01.107

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714:05 - 714:14	Prevoznik, Thomas 04-18-2019 (00:00:15) 714:5 THE WITNESS: To regulate 714:6 a -- regulated transactions, a 714:7 transaction for -- in this 714:8 particular section, regarding 714:9 chemicals. 714:10 BY MR. FARRELL: 714:11 Q. So we are talking about 714:12 List I chemicals, not controlled 714:13 substances? 714:14 A. Correct.	TP01.108
715:04 - 715:11	Prevoznik, Thomas 04-18-2019 (00:00:26) 715:4 So under this report, it's 715:5 my understanding, is that the DEA was 715:6 complying with Section 21 U.S.C. 830, 715:7 which, if you read Paragraph 1(a) out 715:8 loud, requires what? Reports to the 715:9 Attorney General. It says, "Each 715:10 regulated person shall report to the 715:11 Attorney General." And what does A say?	TP01.109
715:14 - 716:03	Prevoznik, Thomas 04-18-2019 (00:00:29) 715:14 THE WITNESS: "Any regulated 715:15 transaction involving an 715:16 extraordinary quantity of a listed 715:17 chemical, an uncommon method of 715:18 payment or delivery, or any other 715:19 circumstance that the regulated 715:20 person believes may indicate that 715:21 the listed chemical will be used 715:22 in violation of this subchapter." 715:23 BY MR. FARRELL: 715:24 Q. So, I'm asking the DEA, the 716:1 Reno report from 1998, its authority 716:2 arises out of the Methamphetamine Act; is 716:3 that right?	TP01.110
716:09 - 716:09	Prevoznik, Thomas 04-18-2019 (00:00:01) 716:9 THE WITNESS: Yes.	TP01.111
716:11 - 716:20	Prevoznik, Thomas 04-18-2019 (00:00:23) 716:11 Q. And the definition of a 716:12 suspicious order under the	TP01.112

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	716:13 Methamphetamine Act is what? What size 716:14 transaction? 716:15 A. The extraordinary quantity. 716:16 Q. All right. Now, controlled 716:17 substances are not governed by the 716:18 methamphetamine act unless they contain 716:19 ephedrine or pseudoephedrine; is that 716:20 right?	
716:24 - 717:02	Prevoznik, Thomas 04-18-2019 (00:00:03)	TP01.113
	716:24 Q. I'm asking you, the DEA? 717:1 A. Yeah. I'm waiting to make 717:2 sure --	
717:06 - 717:06	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.114
	717:6 THE WITNESS: Yes.	
720:08 - 720:11	Prevoznik, Thomas 04-18-2019 (00:00:08)	TP01.115
	720:8 Q. Because it -- comparing a 720:9 List I chemical to a controlled 720:10 substance, is comparing apples to 720:11 oranges; is that fair?	
720:14 - 720:14	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.116
	720:14 THE WITNESS: Yes.	
722:11 - 722:17	Prevoznik, Thomas 04-18-2019 (00:00:22)	TP01.117
	722:11 Okay. So this was discussed 722:12 yesterday. I'm just trying to find 722:13 clarification. 722:14 This Reno report, according 722:15 to this note, applies to List I 722:16 chemicals, agreed? 722:17 A. Yes.	
722:24 - 723:03	Prevoznik, Thomas 04-18-2019 (00:00:15)	TP01.118
	722:24 Q. Second -- secondly, it can 723:1 apply to Control II and Control III 723:2 controlled substances that contain List I 723:3 chemicals. Agreed or disagree?	
723:08 - 723:08	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.119
	723:8 THE WITNESS: Agreed.	
724:12 - 724:20	Prevoznik, Thomas 04-18-2019 (00:00:24)	TP01.120
	724:12 Q. We agree that this 724:13 document we're looking at from the Reno 724:14 report is guidance from the DEA to	

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	724:15 registrants under the Methamphetamine Act 724:16 regarding looking for orders of 724:17 extraordinary size involving List I 724:18 chemicals. That's been established. And 724:19 I'm asking you whether or not you agree 724:20 with it.	
725:01 - 725:01	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.121
	725:1 THE WITNESS: Yes.	
734:19 - 735:06	Prevoznik, Thomas 04-18-2019 (00:00:33) 734:19 Q. Will you continue reading? 734:20 A. "Cardinal Health understood 734:21 DEA to want orders for opioids reported 734:22 that exceeded a calculation endorsed by 734:23 DEA or that a wholesale distributor 734:24 otherwise identified as unusual in size, 735:1 pattern or frequency." 735:2 Q. Are you aware of the DEA 735:3 ever endorsing a calculation for opioids 735:4 to identify orders of unusual size, 735:5 pattern, or frequency? 735:6 A. No.	TP01.122
737:12 - 737:18	Prevoznik, Thomas 04-18-2019 (00:00:25) 737:12 Q. So my question to the DEA, 737:13 is, did the DEA ever provide guidance to 737:14 Cardinal Health that it could use the 737:15 Reno report's definition of suspicious, 737:16 which is extraordinary size, as the 737:17 algorithm for measuring unusual orders of 737:18 controlled substances?	TP01.123
737:22 - 737:23	Prevoznik, Thomas 04-18-2019 (00:00:02) 737:22 THE WITNESS: Not to my 737:23 knowledge.	TP01.124
738:14 - 738:23	Prevoznik, Thomas 04-18-2019 (00:00:37) 738:14 Q. Cardinal Health is stating 738:15 in its discovery responses to the court 738:16 that the DEA provided guidance to them, 738:17 that they could use the Reno report and 738:18 its algorithm for orders of extraordinary 738:19 size to identify unusual orders of 738:20 controlled substances.	TP01.125

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739:04 - 739:11	<p>738:21 Are you aware of the DEA 738:22 providing such guidance to Cardinal 738:23 Health?</p> <p>Prevoznik, Thomas 04-18-2019 (00:00:21)</p>	TP01.126
739:17 - 739:24	<p>739:4 THE WITNESS: I am not 739:5 aware.</p> <p>739:6 BY MR. FARRELL:</p> <p>739:7 Q. Is it the DEA's position 739:8 that using an algorithm for extraordinary 739:9 size is an appropriate measurement of 739:10 orders of unusual size for controlled 739:11 substances?</p> <p>Prevoznik, Thomas 04-18-2019 (00:00:23)</p>	TP01.127
740:05 - 740:05	<p>739:17 THE WITNESS: No.</p> <p>739:18 BY MR. FARRELL:</p> <p>739:19 Q. In fact, in the Reno report, 739:20 the DEA provided recommendation and 739:21 guidance to registrants that it could 739:22 look for orders of extraordinary size of 739:23 List I chemicals using a factor of three. 739:24 Is that correct?</p> <p>Prevoznik, Thomas 04-18-2019 (00:00:01)</p>	TP01.128
747:09 - 747:14	<p>740:5 THE WITNESS: Yes.</p> <p>Prevoznik, Thomas 04-18-2019 (00:00:22)</p> <p>747:9 Q. Has the DEA provided 747:10 guidance to registrants of controlled 747:11 substances that don't include List I 747:12 chemicals that it can multiply the 747:13 monthly average by three to identify 747:14 orders that are merely unusual?</p>	TP01.129
747:19 - 747:20	<p>Prevoznik, Thomas 04-18-2019 (00:00:01)</p> <p>747:19 THE WITNESS: Not to my 747:20 knowledge.</p>	TP01.130
749:06 - 749:12	<p>Prevoznik, Thomas 04-18-2019 (00:00:21)</p> <p>749:6 Has the DEA ever provided 749:7 industrywide guidance that it could use 749:8 the definition of suspicious order for 749:9 the List I chemicals under the 749:10 methamphetamine act for orders of 749:11 controlled substances that do not include</p>	TP01.131

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749:13 - 749:13	749:12 List I chemicals? Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.132
749:20 - 749:20	749:13 A. Not to my knowledge. Prevoznik, Thomas 04-18-2019 (00:00:03)	TP01.133
749:21 - 750:03	749:20 In the context of the first Prevoznik, Thomas 04-18-2019 (00:00:30) 749:21 sentence, has the DEA ever provided 749:22 guidance to registrants, which are, in 749:23 this case, distributors of Control II 749:24 prescription opioids, that it satisfies 750:1 its compliance obligations under federal 750:2 law by submitting after-the-fact 750:3 ingredient limit reports?	TP01.134
750:07 - 750:08	750:7 THE WITNESS: Not to my Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.135
750:10 - 750:13	750:8 knowledge. Prevoznik, Thomas 04-18-2019 (00:00:09) 750:10 Q. Now, you'll recall from the 750:11 1996 diversion investigators manual, if 750:12 you'll flip back to it, which is 750:13 Exhibit 11.	TP01.136
750:14 - 750:19	750:14 A. I'll use mine. The '96 one? 750:15 Q. The '96 one. 750:16 Is there any reference to 750:17 an -- an approved factor to be used by a 750:18 registrant to identify unusual orders of 750:19 controlled substances?	TP01.137
750:22 - 750:22	750:22 THE WITNESS: No. Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.138
752:06 - 752:09	Prevoznik, Thomas 04-18-2019 (00:00:17) 752:6 Q. Would the DEA ever endorse a 752:7 methodology for use by a registrant that 752:8 multiplied a monthly average by four to 752:9 determine orders of unusual size?	TP01.139
752:14 - 752:15	752:14 THE WITNESS: DEA doesn't 752:15 endorse the systems. Prevoznik, Thomas 04-18-2019 (00:00:05)	TP01.140
752:17 - 752:20	752:17 Q. Is using a factor of four Prevoznik, Thomas 04-18-2019 (00:00:10)	TP01.141

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752:24 - 753:01	752:18 when calculating orders of unusual size 752:19 compliant with federal regulations 752:20 according to the DEA? Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.142
755:02 - 755:04	752:24 THE WITNESS: Not to my 753:1 knowledge. Prevoznik, Thomas 04-18-2019 (00:00:07)	TP01.143
755:08 - 755:08	755:2 Q. And is this a true and 755:3 accurate version of the 2004 chemical 755:4 handler's manual published by the DEA? Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.144
755:09 - 755:15	755:8 THE WITNESS: Yes. Prevoznik, Thomas 04-18-2019 (00:00:15) 755:9 BY MR. FARRELL: 755:10 Q. Again, is this a document 755:11 that applies to List I chemicals, 755:12 including ephedrine and pseudoephedrine 755:13 and the chemicals used to make 755:14 methamphetamine? 755:15 A. Yes.	TP01.145
755:20 - 756:01	Prevoznik, Thomas 04-18-2019 (00:00:17) 755:20 Q. Does the DEA provide 755:21 guidance that this document is an 755:22 appropriate reference point for 755:23 monitoring suspicious orders of 755:24 controlled substances that do not include 756:1 List I chemicals?	TP01.146
756:06 - 756:06	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.147
759:19 - 760:02	756:6 THE WITNESS: No. Prevoznik, Thomas 04-18-2019 (00:00:25) 759:19 Q. If a registrant that is a 759:20 wholesale distributor of controlled 759:21 substances, excluding those that contain 759:22 List I chemicals, is using E-3 to 759:23 identify suspicious orders of unusual 759:24 size, frequency or pattern, is that 760:1 compliant with federal law, according to 760:2 the DEA?	TP01.148
760:07 - 760:07	Prevoznik, Thomas 04-18-2019 (00:00:01) 760:7 THE WITNESS: No.	TP01.149

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761:01 - 761:14	Prevoznik, Thomas 04-18-2019 (00:00:52) 761:1 And tell me if you 761:2 recognize this document. 761:3 A. Yes. 761:4 Q. What is it? 761:5 A. It's a letter that DEA sent 761:6 to the distributors, registrants, by 761:7 Joe -- by Joe Rannazzisi who was the head 761:8 of the diversion program of DEA, it's 761:9 dated September 27th, 2006. 761:10 Q. Is this a true and accurate 761:11 copy of the letter sent by the DEA to all 761:12 registrants in the chain of distribution 761:13 of controlled substances? 761:14 A. Yes.	TP01.150
764:01 - 764:04	Prevoznik, Thomas 04-18-2019 (00:00:15) 764:1 Q. So without belaboring the 764:2 point in going through this, is it the 764:3 DEA's position that anything in that 764:4 letter is a new rule?	TP01.151
764:08 - 764:08	Prevoznik, Thomas 04-18-2019 (00:00:01) 764:8 THE WITNESS: No.	TP01.152
765:19 - 766:03	Prevoznik, Thomas 04-18-2019 (00:00:21) 765:19 Is this a true and accurate 765:20 copy of the second Rannazzisi letter sent 765:21 by the DEA to wholesale distributors of 765:22 prescription opioids dated December 27, 765:23 2007? 765:24 A. It went to manufacturers and 766:1 distributors. 766:2 Q. This one did? 766:3 A. Yes.	TP01.153
766:07 - 766:10	Prevoznik, Thomas 04-18-2019 (00:00:11) 766:7 Q. Does the DEA believe that 766:8 there's anything in this letter that 766:9 constitutes a new rule? 766:10 A. No.	TP01.154
768:14 - 768:21	Prevoznik, Thomas 04-18-2019 (00:00:10) 768:14 (Video clip played as 768:15 follows:)	TP01.155

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	768:16 MR. FARRELL: During this 768:17 time frame prior to 2007, did 768:18 Cardinal report orders as 768:19 potentially suspicious or 768:20 suspicious orders, and then still 768:21 send the shipments out?	
768:24 - 769:04	Prevoznik, Thomas 04-18-2019 (00:00:07)	TP01.156
	768:24 THE WITNESS: Yes, that is 769:1 the direction we received from the 769:2 DEA. We made the reports as 769:3 required and there was not a 769:4 shipping requirement.	
770:06 - 770:11	Prevoznik, Thomas 04-18-2019 (00:00:13)	TP01.157
	770:6 Cardinal Health claims that 770:7 it received direction from the DEA that 770:8 it could report suspicious orders and 770:9 then still ship it. 770:10 Is the DEA aware of 770:11 providing such guidance?	
770:17 - 770:18	Prevoznik, Thomas 04-18-2019 (00:00:02)	TP01.158
	770:17 THE WITNESS: Not to my 770:18 knowledge.	
771:07 - 771:10	Prevoznik, Thomas 04-18-2019 (00:00:08)	TP01.159
	771:7 Q. Does the DEA take the 771:8 position that a registrant of controlled 771:9 substances has a duty to block shipments 771:10 of suspicious orders?	
771:14 - 771:17	Prevoznik, Thomas 04-18-2019 (00:00:06)	TP01.160
	771:14 THE WITNESS: Yes. 771:15 BY MR. FARRELL: 771:16 Q. Is that now and always been 771:17 the law in the United States of America?	
771:20 - 771:20	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.161
	771:20 THE WITNESS: Yes.	
772:10 - 772:13	Prevoznik, Thomas 04-18-2019 (00:00:06)	TP01.162
	772:10 Q. Okay. You saw the testimony 772:11 from Cardinal Health. 772:12 Do you believe the testimony 772:13 is accurate?	
772:18 - 772:18	Prevoznik, Thomas 04-18-2019 (00:00:01)	TP01.163

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807:02 - 807:19	<p>772:18 THE WITNESS: No.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:48)</p> <p>807:2 And again, building on the 807:3 testimony from the previous two days without 807:4 repeating it, I'm going to show you the 807:5 bottom right-hand corner is US-DEA-00026146, 807:6 and I'd ask you to read Roman Numeral IX into 807:7 the record.</p> <p>807:8 A. "Single suspicious orders. 807:9 Single orders of unusual size or deviation 807:10 must be reported immediately. The submission 807:11 of a monthly printout of after-the-fact sales 807:12 will not relieve a registrant from the 807:13 responsibility of reporting these single 807:14 excessive or suspicious orders. DEA has 807:15 interpreted 'orders' to mean prior to 807:16 shipment."</p> <p>807:17 Q. So my question to you is, is 807:18 this consistent with the guidance provided by 807:19 the DEA to wholesalers and distributors?</p>	TP01.164
807:24 - 807:24	<p>Prevoznik, Thomas 05-17-2019 (00:00:02)</p>	TP01.165
809:14 - 810:03	<p>807:24 THE WITNESS: Yes.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:32)</p> <p>809:14 Q. Okay. And I've highlighted 809:15 down -- a particular provision for emphasis 809:16 to build on the previous two days' testimony. 809:17 Beginning with "As previously discussed," 809:18 could you read that provision into the 809:19 record?</p> <p>809:20 A. "An after-the-fact computer 809:21 printout of sales data does not relieve a 809:22 registrant of its responsibility to report 809:23 excessive or suspicious orders when 809:24 discovered."</p> <p>809:25 Q. Is this consistent with the 810:1 guidance the DEA has provided to the 810:2 wholesalers and manufacturers of prescription 810:3 opioids?</p>	TP01.166
810:05 - 810:05	<p>Prevoznik, Thomas 05-17-2019 (00:00:01)</p>	TP01.167
	810:5 THE WITNESS: Yes.	

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810:07 - 810:11	Prevoznik, Thomas 05-17-2019 (00:00:15)	TP01.168
810:7	Q. I'm going to show you -- which	
810:8	8 is the last page of this document. And	
810:9	you'll see in the bottom right-hand corner is	
810:10	810 US-DEA-00026150. It has the stamp of May 16,	
810:11	810:11 1984.	
810:16 - 810:18	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.169
810:16	A. It's a letter from Mr. Gitchel,	
810:17	810:17 again, from DEA to the National Wholesales	
810:18	810:18 Druggists' Association.	
810:22 - 811:08	Prevoznik, Thomas 05-17-2019 (00:00:28)	TP01.170
810:22	810:22 and I'd ask for you to read it	
810:23	810:23 into the record.	
810:24	810:24 A. "However, I want to make it	
810:25	810:25 clear that the submission of a monthly	
811:1	811:1 printout of after-the-fact sales will not	
811:2	811:2 relieve a registrant from the responsibility	
811:3	811:3 of reporting excessive or suspicious orders.	
811:4	811:4 DEA has interpreted 'orders' to mean prior to	
811:5	811:5 shipment."	
811:6	811:6 Q. Is this consistent with the	
811:7	811:7 guidance the DEA has provided to wholesalers	
811:8	811:8 and manufacturers of prescription opioids?	
811:11 - 811:11	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.171
811:11	811:11 THE WITNESS: Yes.	
815:09 - 815:14	Prevoznik, Thomas 05-17-2019 (00:00:28)	TP01.172
815:9	815:9 Q. If any distributor of	
815:10	815:10 prescription opioids relies upon	
815:11	815:11 after-the-fact sales reporting as the full	
815:12	815:12 scope of its compliance with 1301.74(b), does	
815:13	815:13 the DEA believe that it's sufficient to	
815:14	815:14 satisfy the obligations under federal law?	
815:18 - 815:18	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.173
815:18	815:18 THE WITNESS: No.	
816:10 - 816:21	Prevoznik, Thomas 05-17-2019 (00:00:30)	TP01.174
816:10	816:10 And I'll direct your attention	
816:11	816:11 to the bottom right-hand corner with the	
816:12	816:12 Bates stamp US-DEA-00026154. It has the	
816:13	816:13 stamp of December 8, 1993, and I'm going to	
816:14	816:14 ask you if you recognize this document.	

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	<p>816:15 A. Yes.</p> <p>816:16 Q. What is this document?</p> <p>816:17 A. This is an internal document</p> <p>816:18 from Gene Haislip, our director of Office and</p> <p>816:19 Diversion Control DEA, to the SAC, or special</p> <p>816:20 agent in charge, of our Dallas field</p> <p>816:21 division.</p>	
820:07 - 820:23	<p>Prevoznik, Thomas 05-17-2019 (00:00:47)</p> <p>820:7 "Section 1301.74(b)," could you read the next</p> <p>820:8 sentence?</p> <p>820:9 A. "1301.74(b) of Title 21 of the</p> <p>820:10 Code of Federal Regulations clearly places</p> <p>820:11 the responsibility for designing and</p> <p>820:12 operating a system to identify suspicious</p> <p>820:13 orders of controlled substances on the</p> <p>820:14 registrant. Implicit in this regulation is</p> <p>820:15 the idea that the registrant should not</p> <p>820:16 merely be accumulating data on what appear to</p> <p>820:17 be excessive purchases for eventual</p> <p>820:18 submission to DEA but rather that the system</p> <p>820:19 be monitored so that any such orders will be</p> <p>820:20 apparent to the registrant so that they -- so</p> <p>820:21 that they can be reported to DEA upon</p> <p>820:22 discovery and, whenever possible, before the</p> <p>820:23 order is shipped."</p>	TP01.175
822:15 - 823:24	<p>Prevoznik, Thomas 05-17-2019 (00:01:44)</p> <p>822:15 Q. Now, at the very bottom, there</p> <p>822:16 is a discussion from the director beginning</p> <p>822:17 with the last paragraph on the bottom of the</p> <p>822:18 page beginning "what is -- what is of</p> <p>822:19 particular concern."</p> <p>822:20 Can you please read that into</p> <p>822:21 the record?</p> <p>822:22 A. "What is of particular concern</p> <p>822:23 to me is the statement that appears on the</p> <p>822:24 report submitted by the McKesson Corporation</p> <p>822:25 in Fort Worth, Texas. For example, 'With the</p> <p>823:1 submission of this report, we are leaving to</p> <p>823:2 the DEA the final determination of whether</p> <p>823:3 they are suspicious or unusual.' This</p>	TP01.176

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	823:4 position is unacceptable and clearly in 823:5 contravention to the requirements of 21 CFR 823:6 1301.74(b). 823:7 "A registrant whose own 823:8 personnel are in the best position to 823:9 determine what is excessive or unusual based 823:10 on knowledge of their customers and usual 823:11 purchasing practices may not abrogate its 823:12 responsibility to identify suspicious orders 823:13 and to determine whether to ship or refuse to 823:14 ship the controlled substance order. 823:15 "The registrant must also 823:16 report any suspicious orders as soon as 823:17 possible to the DEA. This has been conveyed 823:18 to the McKesson national management in San 823:19 Francisco, and they have agreed to remove the 823:20 statement from reports." 823:21 Q. So on behalf of the DEA, can 823:22 you validate that this is a true and accurate 823:23 summary of the conversation between the DEA 823:24 and McKesson?	
824:02 - 824:08	Prevoznik, Thomas 05-17-2019 (00:00:15)	TP01.177
	824:2 THE WITNESS: Yes. 824:3 QUESTIONS BY MR. FARRELL: 824:4 Q. Is this consistent with the 824:5 guidance that DEA provided not only to 824:6 McKesson but to every other wholesale 824:7 distributor and manufacturer of prescription 824:8 opioids?	
824:13 - 824:13	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.178
	824:13 THE WITNESS: Yes.	
834:21 - 834:24	Prevoznik, Thomas 05-17-2019 (00:00:13)	TP01.179
	834:21 So it should go 834:22 AmerisourceBergen first. The top 834:23 right is August 16, 2005, Bates stamp 834:24 US-DEA-00000147.	
840:10 - 840:12	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.180
	840:10 What I'd ask you to do is I'd 840:11 ask you to turn to page 7 of the PowerPoint 840:12 presentation with AmerisourceBergen.	

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840:23 - 841:18	Prevoznik, Thomas 05-17-2019 (00:00:56) 840:23 Q. And if you look at the next 840:24 slide, it states, "Reporting a suspicious 840:25 order to the DEA does not relieve the 841:1 distributor of the responsibility to maintain 841:2 effective controls against diversion." 841:3 Did I read that accurately? 841:4 A. Yes. 841:5 Q. Okay. Why did the DEA put the 841:6 word "not" in all caps? 841:7 A. To emphasize that they had to 841:8 provide the suspicious order, not just -- not 841:9 just after-sales reports. 841:10 Q. The next slide, it says, "The 841:11 DEA cannot tell a distributor if an order is 841:12 legitimate or not" and that "the distributor 841:13 must determine which orders are suspicious 841:14 and make a sales decision." 841:15 Is this similar to all of the 841:16 other slide shows the DEA provided to the 841:17 distributors back in the 2000 -- 2005, 2006 841:18 time frame?	TP01.181
841:21 - 841:21	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.182
	841:21 THE WITNESS: Yes.	
841:23 - 842:04	Prevoznik, Thomas 05-17-2019 (00:00:10) 841:23 Q. In other words, this PowerPoint 841:24 presentation, was it a stock PowerPoint 841:25 presentation that was shown to Cardinal 842:1 Health? 842:2 A. Yes. 842:3 Q. Was it shown to McKesson? 842:4 A. Yes.	TP01.183
842:18 - 842:25	Prevoznik, Thomas 05-17-2019 (00:00:18) 842:18 Q. So I'm also going to have you 842:19 flip to page 12. 842:20 In the summary slides, the very 842:21 last bullet point, can you read what that 842:22 says? 842:23 A. "Not limited to Internet 842:24 pharmacies."	TP01.184

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843:05 - 843:17	<p>842:25 Q. What does that mean?</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:32)</p> <p>843:5 A. It's not just the -- what the Internet pharmacies was, but it would be any pharmacy, retail.</p> <p>843:8 Q. The very next slide, it says, "A pattern of drugs being distributed to pharmacies who are diverting controlled substances demonstrates the lack of effective controls against diversion by the distributor."</p> <p>843:14 This PowerPoint presentation in the distributor initiative meeting, it was not just limited to rogue Internet pharmacies, was it?</p>	TP01.185
843:20 - 843:23	<p>Prevoznik, Thomas 05-17-2019 (00:00:09)</p> <p>843:20 THE WITNESS: No. The emphasis was regarding the Internet, but it was for the totality of their responsibilities as a registrant.</p>	TP01.186
845:18 - 846:04	<p>Prevoznik, Thomas 05-17-2019 (00:00:33)</p> <p>845:18 Q. So the next plaintiff's exhibit has the Bates stamp at the bottom corner of US-DEA-00000371, and you'll see that it's dated January 23, 2006, but it's referencing a January 3, 2006 meeting.</p> <p>845:23 Do you see that?</p> <p>845:24 A. Yes.</p> <p>845:25 Q. And in it you can see where it looks like it contains -- this is the memorandum of the meeting between McKesson and the DEA as a result of the distributor initiative. Agreed?</p>	TP01.187
846:07 - 847:04	<p>Prevoznik, Thomas 05-17-2019 (00:01:06)</p> <p>846:7 THE WITNESS: Yes.</p> <p>846:8 QUESTIONS BY MR. FARRELL:</p> <p>846:9 Q. Now, what I'm going to ask you to do is I'm going to ask you to go to the end of page 2. And at the bottom, starting with the word "after," the very last</p>	TP01.188

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	846:13 paragraph, I'd ask you to read that into the 846:14 record.	
	846:15 A. "After the conclusion of this 846:16 meeting, it was learned from Gary Hilliard of 846:17 McKesson Corp that one of the reasons they 846:18 were not able to realize the full volume of 846:19 hydrocodone product going out to the Florida 846:20 pharmacies was that their reports only 846:21 included the name brand hydrocodone products 846:22 distributed and was leaving out the generic 846:23 products."	
	846:24 Q. The next sentence.	
	846:25 A. "It was only after realizing 847:1 that the generic were not being reported was 847:2 McKesson Corp then able to see the large 847:3 quantities that DEA was bringing to 847:4 McKesson's attention."	
847:17 - 847:22	Prevoznik, Thomas 05-17-2019 (00:00:20)	TP01.189
	847:17 Q. This document, following the 847:18 distributor initiative meeting between the 847:19 DEA and McKesson, appears to present the fact 847:20 that the DEA discovered McKesson was only 847:21 tracking brand name prescription opiates.	
	847:22 A. Correct.	
848:03 - 848:06	Prevoznik, Thomas 05-17-2019 (00:00:15)	TP01.190
	848:3 Q. If, in fact, McKesson was only 848:4 tracking brand name prescription opiates and 848:5 leaving out the generic products, is that a 848:6 violation of federal law?	
848:10 - 848:10	Prevoznik, Thomas 05-17-2019 (00:00:02)	TP01.191
	848:10 THE WITNESS: Yes.	
849:12 - 849:14	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.192
	849:12 Q. All right. On a scale of 0 of 849:13 10 of screw-ups, how big of a screw-up is 849:14 this?	
849:22 - 850:01	Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.193
	849:22 THE WITNESS: In my personal 849:23 capacity, a big one, a really big one.	
	849:24 QUESTIONS BY MR. FARRELL:	
	849:25 Q. Epic?	

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850:18 - 851:09	<p>850:1 A. Yes.</p> <p>Prevoznik, Thomas 05-17-2019 (00:01:10)</p> <p>850:18 Q. Now, without having to go 850:19 through all of the nuances, what I'm going to 850:20 ask you to do is I'm going to make a 850:21 reference now. At the bottom right-hand 850:22 corner is Bates stamp CAH_MDL2804_01376799. 850:23 Do you see that? 799 are the 850:24 last three numbers.</p> <p>850:25 A. Yes, I have it.</p> <p>851:1 Q. Now, in it, in this letter, 851:2 Larry -- to Larry Cote from Cardinal Health's 851:3 lawyers, it seems to indicate that controlled 851:4 substances that are sold by Cardinal Health 851:5 to CVS, Walgreens, Kroger, Kmart and Winn 851:6 Dixie, which are large, national or regional 851:7 chains, pose no threat of diversion due to 851:8 their sophisticated anti-diversion systems 851:9 and historical record of compliance.</p>	TP01.194
851:13 - 851:16	<p>Prevoznik, Thomas 05-17-2019 (00:00:03)</p> <p>851:13 THE WITNESS: Yes.</p> <p>851:14 QUESTIONS BY MR. FARRELL:</p> <p>851:15 Q. Did I read that accurately?</p> <p>851:16 A. Yes.</p>	TP01.195
851:20 - 851:23	<p>Prevoznik, Thomas 05-17-2019 (00:00:12)</p> <p>851:20 Q. Aside from me reading that 851:21 accurately, is it true that large, national, 851:22 regional chains of pharmacies pose no threat 851:23 of diversion of prescription opioids?</p>	TP01.196
852:01 - 852:06	<p>Prevoznik, Thomas 05-17-2019 (00:00:12)</p> <p>852:1 THE WITNESS: It's not true.</p> <p>852:2 QUESTIONS BY MR. FARRELL:</p> <p>852:3 Q. In fact, the DEA has 852:4 investigated and prosecuted many of the large 852:5 national or regional chains, including CVS 852:6 and Walgreens?</p>	TP01.197
852:14 - 852:14	<p>Prevoznik, Thomas 05-17-2019 (00:00:01)</p> <p>852:14 THE WITNESS: Yes.</p>	TP01.198
853:04 - 853:10	<p>Prevoznik, Thomas 05-17-2019 (00:00:32)</p> <p>853:4 Q. Does the DEA consider -- if a</p>	TP01.199

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	853:5 wholesale distributor came to the DEA and 853:6 said, "I've got a new customer and it's CVS, 853:7 which is a national chain store, and because 853:8 they have such swell security, I don't want 853:9 to monitor them for suspicious orders. Is 853:10 that okay?"	
853:19 - 853:20	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.200
	853:19 THE WITNESS: They can't do 853:20 that.	
854:19 - 854:25	Prevoznik, Thomas 05-17-2019 (00:00:17)	TP01.201
	854:19 Q. All right. Would the DEA 854:20 provide guidance to such a wholesale 854:21 distributor, that regardless of whether its 854:22 customer is a national chain pharmacy, the 854:23 distributor still must comply with 854:24 1301.74(b)? 854:25 A. Yes.	
863:05 - 863:10	Prevoznik, Thomas 05-17-2019 (00:00:13)	TP01.202
	863:5 So here you'll see the NWDA 863:6 suspicious order monitoring system, which we 863:7 were shown as Exhibit 18. 863:8 Is that familiar to you? 863:9 A. Yes. 863:10 Q. Okay. So in 1984 --	
863:16 - 863:19	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.203
	863:16 MS. SINGER: I'm sorry. Oh, 863:17 I'm sorry, the new exhibit is 29. The 863:18 backup of the whole policy is 863:19 Exhibit 18.	
863:22 - 864:23	Prevoznik, Thomas 05-17-2019 (00:01:05)	TP01.204
	863:22 Q. Okay. And just directing your 863:23 attention very quickly to 2, sub 2, on your 863:24 monitor -- I'm sorry, 9 on your monitor, 863:25 single suspicious orders, is it correct that 864:1 this suspicious order monitoring system 864:2 publication from 1984 established that 864:3 "single orders of unusual size or deviation 864:4 must be reported immediately, the submission 864:5 of monthly printout of after-the-fact sales 864:6 will not relieve a registrant from the	

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	<p>864:7 responsibility of reporting these single 864:8 excessive or suspicious orders. DEA has 864:9 interpreted orders to mean prior to 864:10 shipment"?</p> <p>864:11 Does that accurately reflect 864:12 the policy of the DEA?</p> <p>864:13 A. Yes.</p> <p>864:14 Q. And that's as of 1984, correct?</p> <p>864:15 A. Correct.</p> <p>864:16 Q. All right. Turning next to 864:17 1987 is our next marker in the timeline.</p> <p>864:18 And I'm sorry, just to be 864:19 perfectly clear, from 1971 to the present, 864:20 when the Controlled Substances Act was first 864:21 enacted in '71, has it been the DEA's 864:22 position that ILRs are not suspicious order 864:23 reports?</p>	
864:25 - 865:05	<p>Prevoznik, Thomas 05-17-2019 (00:00:10)</p> <p>864:25 THE WITNESS: Yes.</p> <p>865:1 QUESTIONS BY MS. SINGER:</p> <p>865:2 Q. And do ILRs relieve a 865:3 registrant -- does submitting ILRs relieve a 865:4 registrant of the obligation to report 865:5 suspicious orders?</p>	TP01.205
865:07 - 866:01	<p>Prevoznik, Thomas 05-17-2019 (00:00:49)</p> <p>865:7 THE WITNESS: No.</p> <p>865:8 QUESTIONS BY MS. SINGER:</p> <p>865:9 Q. All right. The next marker, 865:10 1987, is that seminar report which was 865:11 Prevoznik 17, and that established any system 865:12 must be capable of both detecting individual 865:13 orders or -- which are suspicious orders, 865:14 which become suspicious over time due to 865:15 frequency, quantity or pattern.</p> <p>865:16 Is that consistent with the 865:17 DEA's policy?</p> <p>865:18 A. Yes.</p> <p>865:19 Q. And the DEA pointed out that 865:20 the company is still responsible under their 865:21 registrations for acting in the public</p>	TP01.206

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865:22 interest, reporting the order does not in any 865:23 way relieve the firm from the responsibility 865:24 for the shipment. 865:25 Does that also reflect the 866:1 DEA's policy consistently over time? 866:04 - 866:04 Prevoznik, Thomas 05-17-2019 (00:00:01) TP01.207 866:4 THE WITNESS: Yes.		
868:17 - 870:21 Prevoznik, Thomas 05-17-2019 (00:02:00) TP01.208 868:17 Q. All right. I'd like to 868:18 turn your attention to Section 5126, which is 868:19 Bates number ending 301. 868:20 And I'm sorry, the Bates number 868:21 for this document is CAH_MDL_PRIOR 868:22 PRODUCTION_DEA07_01176247. 868:23 All right. So turning to 301, 868:24 which I think has been tabbed in your copy, 868:25 Mr. Prevoznik. 869:1 A. Yep. 869:2 Q. All right. Can you read the 869:3 third paragraph beginning "registrants"? 869:4 A. "Registrants who routinely 869:5 report suspicious orders, yet fill these 869:6 orders with reason to believe they are 869:7 destined for the illicit market, are 869:8 expressing an attitude of irresponsibility 869:9 that is a detriment to the public health and 869:10 safety as set forth in 21 USC 823 and 824." 869:11 Q. And 21 USC 823 and 824 the 869:12 Controlled Substances Act? 869:13 A. Yes. 869:14 Q. Okay. And does that statement 869:15 that you just read accurately reflect the 869:16 policy of the DEA in 1990? 869:17 A. Yes. 869:18 Q. And has that remained true 869:19 since then? 869:20 A. Yes. 869:21 Q. Okay. And then read from there 869:22 "suspicious orders"? 869:23 A. "Suspicious orders include		

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	869:24 those which are in excess of legitimate 869:25 medical use or exhibit characteristics 870:1 leading to possible diversion, such as orders 870:2 of unusual size, unusual frequency, or those 870:3 deviating substantially from the -- from a 870:4 normal pattern." 870:5 Q. And keep going. 870:6 A. "The supplier can determine 870:7 whether the order is excessive by checking 870:8 their own sales and establishing the average 870:9 amount of controlled substances shipped to 870:10 registrants of the same apparent size in a 870:11 particular geographic area. If the customer 870:12 exceeds this threshold, the request should be 870:13 viewed as suspicious." 870:14 Q. One more sentence. 870:15 A. "This activity over extended 870:16 periods of time would lead a reasonable 870:17 person to believe that controlled substances 870:18 possibly are being diverted." 870:19 Q. And does the passage you just 870:20 read again reflect the DEA's policy? 870:21 A. Yes.	
875:13 - 875:17	Prevoznik, Thomas 05-17-2019 (00:00:14)	TP01.209
	875:13 Q. All right. So Exhibit 35 is 875:14 the NWDA Controlled Substances Manual, Bates 875:15 number HDA_MDL_000219360. 875:16 Mr. Prevoznik, have you seen 875:17 that document before?	
875:18 - 875:18	Prevoznik, Thomas 05-17-2019 (00:00:02)	TP01.210
	875:18 A. It looks familiar.	
878:07 - 878:18	Prevoznik, Thomas 05-17-2019 (00:00:21)	TP01.211
	878:7 Q. It says there, "Distributors 878:8 are responsible for designing and operating a 878:9 system that will disclose to the distributor 878:10 suspicious orders." 878:11 Do you agree that that is the 878:12 distributor's responsibility? 878:13 A. Yes. 878:14 Q. Okay. And then the note, "Many	

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	878:15 distributors have been cited for failing to 878:16 establish and maintain such a system." 878:17 Is that also accurate? 878:18 A. Yes.	
878:22 - 879:09	Prevoznik, Thomas 05-17-2019 (00:00:31) 878:22 Q. Move to the next paragraph. 878:23 "Distributor establishing suspicious order 878:24 criteria. Distributors should establish 878:25 written criteria of what constitutes a 879:1 suspicious order. DEA leaves it to the 879:2 distributor to make this determination. The 879:3 key for the distributor is to establish 879:4 reasonable criteria based upon customer 879:5 purchasing patterns and then to adhere to 879:6 them in monitoring orders." 879:7 Does that several-step passage 879:8 that I just read accurately reflect a 879:9 distributor's duties under the CSA?	TP01.212
879:13 - 879:13	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.213
879:15 - 879:18	879:13 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:10) 879:15 Q. And do you see in this 879:16 description of suspicious order criteria any 879:17 expression of confusion or lack of clarity 879:18 about what a suspicious order is?	TP01.214
879:22 - 879:22	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.215
880:04 - 880:15	879:22 THE WITNESS: No. Prevoznik, Thomas 05-17-2019 (00:00:26) 880:4 Q. Okay. So it says here, 880:5 "Establish trigger levels, close quote, that 880:6 only kick out purchasers buying substantially 880:7 above the average for an item. The trigger 880:8 level is established by multiplying the 880:9 calculated average by an arbitrary factor. 880:10 It is recommended that at the outset three 880:11 times the average be used for ARCOS items and 880:12 four times the average for non-ARCOS items." 880:13 Do you see where I've just 880:14 read? 880:15 A. Yes.	TP01.216

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881:01 - 881:04	Prevoznik, Thomas 05-17-2019 (00:00:10) 881:1 Q. Is it DEA's position that a 881:2 fixed multiplier of order levels is 881:3 sufficient as a system to identify suspicious 881:4 orders?	TP01.217
881:06 - 881:08	Prevoznik, Thomas 05-17-2019 (00:00:03) 881:6 THE WITNESS: It could be one 881:7 criteria, but it can't be the only 881:8 one.	TP01.218
881:10 - 881:18	Prevoznik, Thomas 05-17-2019 (00:00:22) 881:10 Q. Okay. And it says here, if you 881:11 keep reading on, "After the monitoring 881:12 program has been tested with live data and 881:13 the results analyzed, it may be necessary to 881:14 revise the factors." 881:15 Is it DEA's position that 881:16 distributors have an obligation to make sure 881:17 that any trigger or threshold they use 881:18 actually identifies suspicious orders?	TP01.219
881:23 - 881:23	Prevoznik, Thomas 05-17-2019 (00:00:01) 881:23 THE WITNESS: Yes.	TP01.220
882:10 - 882:17	Prevoznik, Thomas 05-17-2019 (00:00:17) 882:10 Q. Keep going. 882:11 A. "In these situations, DEA 882:12 should be notified before the order is 882:13 shipped, and a copy of all such orders should 882:14 be maintained in the distributor's suspicious 882:15 orders file, with a notation reflecting the 882:16 date and person contacted at DEA as well as 882:17 any guidance received."	TP01.221
882:18 - 882:23	Prevoznik, Thomas 05-17-2019 (00:00:10) 882:18 Q. Go ahead and finish the 882:19 paragraph, please. 882:20 A. "The file also should indicate 882:21 whether the order was shipped. DEA usually 882:22 leaves the responsibility for determining 882:23 whether to ship to the distributor."	TP01.222
882:24 - 883:03	Prevoznik, Thomas 05-17-2019 (00:00:13) 882:24 Q. And does this statement that 882:25 you just read from the NWDA manual of 1997	TP01.223

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883:05 - 883:05	883:1 accurately describe the DEA's position on 883:2 what distributors should be -- or what 883:3 registrants should be doing? Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.224
884:01 - 884:16	883:5 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:30) 884:1 Q. Okay. And there it -- the 884:2 first sentence reads, "DEA has not provided a 884:3 clear definition of what constitutes a 884:4 suspicious order." 884:5 Now that relates to a 884:6 suspicious order of List I chemicals, 884:7 correct? 884:8 A. Correct. 884:9 Q. Okay. And there NWDA is saying 884:10 we don't have a clear definition, correct? 884:11 A. Correct. 884:12 Q. And we didn't see that earlier 884:13 in the manual, correct? 884:14 A. Correct. 884:15 Q. All right. Then let's move to 884:16 Appendix M, which is one more page. Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.225
884:17 - 884:18	884:17 "What does DEA 884:18 consider to be a suspicious order?" Prevoznik, Thomas 05-17-2019 (00:00:11)	TP01.226
888:13 - 888:17	888:13 Q. And would DEA expect 888:14 that a registrant would remain -- excuse me, 888:15 would maintain copies of a suspicious order 888:16 reported to the DEA? 888:17 A. Yes.	TP01.227
889:22 - 890:02	Prevoznik, Thomas 05-17-2019 (00:00:18) 889:22 QUESTIONS BY MS. SINGER: 889:23 Q. All right. Now, we think about 889:24 suspicious orders under CFR 1301.74, but the 889:25 registrant that ships suspicious orders also 890:1 fails to maintain effective controls to 890:2 prevent diversion; is that correct?	TP01.228
890:06 - 890:06	Prevoznik, Thomas 05-17-2019 (00:00:01) 890:6 THE WITNESS: Correct.	TP01.229

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890:23 - 891:02	Prevoznik, Thomas 05-17-2019 (00:00:13) 890:23 Q. Would it make sense to the DEA 890:24 that a registrant could identify an order as 890:25 suspicious, report it to the DEA, not dispel 891:1 their suspicion, and then go ahead and ship 891:2 it so that it could be sold or used?	TP01.230
891:07 - 891:08	Prevoznik, Thomas 05-17-2019 (00:00:02) 891:7 THE WITNESS: No, it would not 891:8 be correct.	TP01.231
891:10 - 891:12	Prevoznik, Thomas 05-17-2019 (00:00:04) 891:10 Q. Why? 891:11 A. Because they're not maintaining 891:12 effective controls over diversion.	TP01.232
891:15 - 891:16	Prevoznik, Thomas 05-17-2019 (00:00:04) 891:15 Q. And what happens if they go 891:16 ahead and just ship that suspicious order?	TP01.233
891:20 - 892:15	Prevoznik, Thomas 05-17-2019 (00:00:45) 891:20 THE WITNESS: Well, it's -- 891:21 there was a -- there was a reason it 891:22 triggered the suspicion, so the 891:23 possibility or potential for it to be 891:24 diverted into the illicit market is 891:25 enhanced because it triggered a 892:1 suspicious order within their system. 892:2 So that being the underlying 892:3 cause for it to be triggered, that -- 892:4 the potential for it to be diverted, 892:5 now it's going -- the potential now is 892:6 greater than it's going into the 892:7 public and is going to affect the 892:8 public health and safety. 892:9 QUESTIONS BY MS. SINGER: 892:10 Q. Okay. And would going ahead 892:11 and shipping suspicious orders demonstrate an 892:12 attitude of irresponsibility, which I think 892:13 is the language of the Diversion 892:14 Investigators Manual, to the detriment of the 892:15 public health?	TP01.234
892:20 - 892:24	Prevoznik, Thomas 05-17-2019 (00:00:10) 892:20 THE WITNESS: Yes.	TP01.235

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	892:21 QUESTIONS BY MS. SINGER: 892:22 Q. And has that always been true, 892:23 that shipping a suspicious order is a failure 892:24 of effective controls to prevent diversion?	
893:02 - 893:02	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.236
893:12 - 893:16	893:2 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:14) 893:12 And, Mr. Prevoznik, can I 893:13 direct you -- and this is the deposition of 893:14 Tom Prevoznik, April 17, 2019. 893:15 All right. And if you could 893:16 turn to page 171. All right. And I want to	TP01.237
893:17 - 893:22	Prevoznik, Thomas 05-17-2019 (00:00:16) 893:17 direct your attention to the middle of the 893:18 page where you testify: "It was a business 893:19 decision on whether to ship or not ship, that 893:20 we, DEA, were not going to direct a 893:21 registrant don't ship or not ship at that 893:22 time."	TP01.238
894:03 - 894:14	Prevoznik, Thomas 05-17-2019 (00:00:23) 894:3 Q. Okay. And then if you turn the 894:4 page -- I'm sorry. At the bottom of 894:5 page 171, because -- so in 7, it was clear 894:6 that you were now directing registrants: Do 894:7 not ship. 894:8 And you said, right, because of 894:9 the Internet. 894:10 And then there's a question: 894:11 "And prior to December 2007, it was a 894:12 business decision by each registrant 894:13 recognizing what their own obligations were, 894:14 correct?"	TP01.239
894:16 - 894:16	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.240
894:20 - 894:23	894:16 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:17) 894:20 Q. And I just want to be clear. 894:21 Between -- before and after 2007, was it 894:22 always the policy of the DEA that registrants 894:23 could not ship suspicious orders?	TP01.241
895:02 - 895:02	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.242

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897:10 - 897:14	895:2 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:18)	TP01.472
	897:10 Q. Okay. And I want to make sure 897:11 that your testimony is clear. When you say 897:12 whether a suspicious order is subjective, do 897:13 you mean that it varies from case to case, or 897:14 it depends on who's looking at it?	
897:17 - 897:23	Prevoznik, Thomas 05-17-2019 (00:00:14)	TP01.473
	897:17 THE WITNESS: Both, really. It 897:18 depends who's looking at it and 897:19 what system do they have that's 897:20 triggering the suspicious order. So 897:21 it's whatever that registrant 897:22 designed, which is specific to that 897:23 registration.	
899:21 - 899:22	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.243
	899:21 Q. Okay. Let's turn very quickly 899:22 to the industry compliance guidelines.	
899:23 - 900:01	Prevoznik, Thomas 05-17-2019 (00:00:13)	TP01.244
	899:23 All right. I'm going to show 899:24 you what's been marked as Exhibit 39. 899:25 And this is Bates number 900:1 CAH_MDL2804_00988458.	
900:05 - 900:09	Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.245
	900:5 Q. Okay. And do you recognize 900:6 this to be the Healthcare Distribution 900:7 Management Association's industry compliance 900:8 guidelines? 900:9 A. Yes.	
900:22 - 901:08	Prevoznik, Thomas 05-17-2019 (00:00:24)	TP01.246
	900:22 Q. Okay. And if you look at the 900:23 first page, the third paragraph: "At the 900:24 center of a sophisticated supply chain, 900:25 distributors are uniquely situated to perform 901:1 due diligence in order to help support the 901:2 security of the controlled substances they 901:3 deliver to their customers." 901:4 Do you see what I've just read? 901:5 A. Yes. 901:6 Q. And does the DEA agree with	

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903:05 - 903:21	<p>901:7 that statement?</p> <p>901:8 A. Yes.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:29)</p> <p>903:5 Under the first paragraph,</p> <p>903:6 Introduction: "Before opening an account" --</p> <p>903:7 do you see where I am?</p> <p>903:8 A. Yes.</p> <p>903:9 Q. -- "the distributor should,</p> <p>903:10 one, obtain background information on the</p> <p>903:11 customer and the customer's business; review</p> <p>903:12 that information carefully and, where</p> <p>903:13 appropriate, verify that information; and</p> <p>903:14 independently investigate the potential</p> <p>903:15 customer."</p> <p>903:16 Do you see what I've just read?</p> <p>903:17 A. Yes.</p> <p>903:18 Q. And does the DEA agree that</p> <p>903:19 those are appropriate and necessary steps for</p> <p>903:20 a registrant to take before shipping</p> <p>903:21 controlled substances?</p>	TP01.247
903:23 - 903:23	<p>Prevoznik, Thomas 05-17-2019 (00:00:01)</p>	TP01.248
904:05 - 904:10	<p>903:23 THE WITNESS: Yes.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:09)</p> <p>904:5 Q. And that should cover the</p> <p>904:6 average number of prescriptions filled each</p> <p>904:7 day, average number of CS item prescriptions</p> <p>904:8 filled each day.</p> <p>904:9 Do you see where I am?</p> <p>904:10 A. Yes.</p>	TP01.249
904:18 - 904:25	<p>Prevoznik, Thomas 05-17-2019 (00:00:13)</p> <p>904:18 Q. Okay. And then percentage of</p> <p>904:19 controlled substances purchased compared to</p> <p>904:20 overall purchases?</p> <p>904:21 A. Yes.</p> <p>904:22 Q. Would the DEA agree that those</p> <p>904:23 are things that a registrant should be</p> <p>904:24 looking at before shipping controlled</p> <p>904:25 substances to a new customer?</p>	TP01.250
905:02 - 905:13	<p>Prevoznik, Thomas 05-17-2019 (00:00:32)</p> <p>905:2 THE WITNESS: Yes.</p>	TP01.251

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905:3 - 905:15	905:3 QUESTIONS BY MS. SINGER: 905:4 Q. All right. And turning to the 905:5 next page, identify -- bottom bullet: 905:6 "Identification of physicians and other 905:7 treatment centers that are the potential 905:8 customer's most frequent prescribers or 905:9 highest purchasing doctors." 905:10 Do you see where I am? 905:11 A. Yes. 905:12 Q. And is that something that a 905:13 registrant should be doing as well? Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.252
906:11 - 906:14	905:15 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.253
906:17 - 907:07	906:11 Q. And merely checking to see 906:12 whether a customer has a DEA registration, 906:13 would that be sufficient due diligence or 906:14 knowing your customer? Prevoznik, Thomas 05-17-2019 (00:00:31)	TP01.254
907:10 - 907:10	906:17 THE WITNESS: No. 906:18 QUESTIONS BY MS. SINGER: 906:19 Q. And it says here under 906:20 Additional Recommendations and Documentation, 906:21 the third bullet, "The performance and 906:22 results of all steps in the customer review 906:23 process should be fully documented as to each 906:24 potential customer, and such documentation 906:25 should be retained in an appropriate file." 907:1 Do you see what I've just read? 907:2 A. Yes. 907:3 Q. And does the DEA also agree 907:4 that that is an appropriate element, that 907:5 documenting due diligence or knowing your 907:6 customer is an appropriate element of that 907:7 program? Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.255
907:16 - 907:22	907:10 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:21)	TP01.256
	907:16 Q. Okay. So it says here that 907:17 distributors -- I'm down at the second set of	

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	907:18 bullets, the bottom bullet: "Thresholds for 907:19 all new customer accounts should be 907:20 established at the lowest level indicated by 907:21 information obtained during the know your 907:22 customer due diligence review."	
908:01 - 908:02	Prevoznik, Thomas 05-17-2019 (00:00:04)	TP01.257
	908:1 Q. And does the DEA agree that 908:2 that is appropriate?	
908:05 - 908:15	Prevoznik, Thomas 05-17-2019 (00:00:26)	TP01.258
	908:5 THE WITNESS: I guess my 908:6 concern would be that if you're -- 908:7 what is the lowest level? Is it what 908:8 the customer is reporting what they 908:9 said they ordered or is it -- you 908:10 know, it could be like really a large 908:11 amount, or is the registrant saying 908:12 this is what we are going to say is 908:13 the lowest amount. 908:14 So I have a little trouble with 908:15 that one.	
908:17 - 908:20	Prevoznik, Thomas 05-17-2019 (00:00:12)	TP01.259
	908:17 Q. Okay. So just making sure that 908:18 we get this clear for the jury, the amount 908:19 that a customer reports may be too high, 908:20 correct?	
908:25 - 908:25	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.260
	908:25 THE WITNESS: Yes.	
909:02 - 909:06	Prevoznik, Thomas 05-17-2019 (00:00:10)	TP01.261
	909:2 Q. And the registrant should be 909:3 making its own judgment about what is not 909:4 suspicious for a particular customer and not 909:5 just accepting what they've previously 909:6 ordered, correct?	
909:09 - 909:12	Prevoznik, Thomas 05-17-2019 (00:00:06)	TP01.262
	909:9 THE WITNESS: Correct. 909:10 QUESTIONS BY MS. SINGER: 909:11 Q. And they shouldn't be building 909:12 in some excess above that level, correct?	
909:15 - 909:15	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.263
	909:15 THE WITNESS: Yes.	

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910:04 - 910:08	Prevoznik, Thomas 05-17-2019 (00:00:10) 910:4 Q. And does the DEA agree that a 910:5 registrant should not just be looking at a 910:6 customer's controlled substances orders but 910:7 their controlled substance orders relative to 910:8 other products they're ordering?	TP01.264
910:11 - 910:11	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.265
912:23 - 912:25	910:11 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:07) 912:23 Q. And it -- again, that is the -- 912:24 that is what the Controlled Substances Act 912:25 requires, correct?	TP01.266
913:04 - 913:04	Prevoznik, Thomas 05-17-2019 (00:00:01) 913:4 THE WITNESS: Correct.	TP01.267
913:13 - 913:17	Prevoznik, Thomas 05-17-2019 (00:00:14) 913:13 Q. And does the DEA agree that a 913:14 registrant should have appropriately trained 913:15 and experienced compliance staff executing 913:16 its suspicious order monitoring and due 913:17 diligence process?	TP01.268
913:21 - 913:21	Prevoznik, Thomas 05-17-2019 (00:00:01) 913:21 THE WITNESS: Yes.	TP01.269
913:23 - 914:08	Prevoznik, Thomas 05-17-2019 (00:00:31) 913:23 Q. All right. Bates number 468, 913:24 subsection D, Documentation, it says under 913:25 that, "All investigations should be fully 914:1 documented, and all records of the 914:2 investigation should be retained in an 914:3 appropriate location within the firm, such as 914:4 with other records relating to the particular 914:5 customer." 914:6 Does the DEA agree with that 914:7 element of a compliant suspicious order 914:8 monitoring program?	TP01.270
914:11 - 914:11	Prevoznik, Thomas 05-17-2019 (00:00:01) 914:11 THE WITNESS: Yes.	TP01.271
916:14 - 916:18	Prevoznik, Thomas 05-17-2019 (00:00:13) 916:14 Q. Now, if an order is identified 916:15 as suspicious and not shipped but then held, 916:16 you know, not shipped, held until the next	TP01.272

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	916:17 month when a threshold resets, is that order 916:18 still suspicious?	
916:24 - 916:24	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.273
	916:24 THE WITNESS: Yes.	
917:02 - 917:03	Prevoznik, Thomas 05-17-2019 (00:00:03)	TP01.274
	917:2 Q. And should the registrant be 917:3 shipping that the next month?	
917:07 - 917:08	Prevoznik, Thomas 05-17-2019 (00:00:03)	TP01.275
	917:7 Q. Without first dispelling the 917:8 suspicion?	
917:12 - 917:14	Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.276
	917:12 THE WITNESS: Yes, they should 917:13 be relieving -- or ascertaining is 917:14 there suspicion or not.	
917:16 - 917:18	Prevoznik, Thomas 05-17-2019 (00:00:04)	TP01.277
	917:16 Q. And not shipping unless they 917:17 eliminate the basis for that suspicion? 917:18 A. Correct.	
917:23 - 918:22	Prevoznik, Thomas 05-17-2019 (00:00:56)	TP01.278
	917:23 Q. 469, sub F, Future Customer 917:24 Orders. "In instances where a distributor 917:25 concludes that an order is or remains 918:1 suspicious after conducting an investigation, 918:2 in addition to notifying DEA, it is 918:3 recommended that the distributor evaluate its 918:4 business relationship with the customer that 918:5 placed that order." 918:6 Do you see what I've just read? 918:7 A. Yes. 918:8 Q. "The distributor may consider 918:9 whether to subject future orders from that 918:10 same customer -- from that same customer for 918:11 the same drug code product or all controlled 918:12 substances to more rigorous scrutiny than was 918:13 applied before the determination that the 918:14 order is suspicious. The distributor may 918:15 also consider whether to cease filling all 918:16 future orders of that drug product code or 918:17 all controlled substances placed by that 918:18 customer."	

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	918:19 Does the DEA agree that when a 918:20 registrant identifies a suspicious order, 918:21 they should also be looking more generally at 918:22 that customer?	
918:25 - 918:25	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.279
	918:25 THE WITNESS: Yes.	
919:02 - 919:04	Prevoznik, Thomas 05-17-2019 (00:00:06)	TP01.280
	919:2 Q. And making a decision as to not 919:3 only whether to fill that order but to 919:4 continue filling orders for that customer?	
919:07 - 919:07	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.281
	919:7 THE WITNESS: Yes.	
920:13 - 920:23	Prevoznik, Thomas 05-17-2019 (00:00:22)	TP01.282
	920:13 Q. All right. Subsection B on 920:14 Bates number 470, under Correspondence For 920:15 Reporting, "It is recommended that all 920:16 correspondence to DEA containing reports of 920:17 suspicious orders should be sent registered 920:18 mail with a return receipt requested, by 920:19 electronic mail or by another system that 920:20 creates for the distributor a permanent 920:21 record that DEA has received the 920:22 notification."	
	920:23 Does the DEA agree with that?	
921:01 - 921:21	Prevoznik, Thomas 05-17-2019 (00:00:40)	TP01.283
	921:1 THE WITNESS: Well, we have two 921:2 different things going on. We have 921:3 those that report to the field and 921:4 those that have been under an action 921:5 that is now dictated to go through 921:6 electronically to headquarters. 921:7 So, yes, if it's going to the 921:8 office, that would be a great way to 921:9 do it, to track that.	
	921:10 QUESTIONS BY MS. SINGER:	
	921:11 Q. Okay. And that C, 921:12 Documentation, "All additional contact with 921:13 DEA, either by telephone or in person, should 921:14 be documented, and a record of the contact 921:15 should be maintained."	

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921:16 - 922:11	<p>921:16 Does the DEA agree with that?</p> <p>921:17 A. Yes.</p> <p>921:18 Q. And is it fair to say that the</p> <p>921:19 DEA would agree that a registrant should be</p> <p>921:20 maintaining records of suspicious orders they</p> <p>921:21 report to the DEA?</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:30)</p>	TP01.284
922:14 - 922:14	<p>921:25 THE WITNESS: Yes.</p> <p>922:1 QUESTIONS BY MS. SINGER:</p> <p>922:2 Q. So while registrants, in going</p> <p>922:3 through all of these different elements of</p> <p>922:4 the industry compliance guidelines, which</p> <p>922:5 we're now thankfully finished with, would the</p> <p>922:6 DEA agree that whatever suspicious order</p> <p>922:7 monitoring algorithm or system that a</p> <p>922:8 registrant uses, that all of these elements</p> <p>922:9 we just went through are elements of a</p> <p>922:10 responsible and compliant program to prevent</p> <p>922:11 diversion?</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:01)</p>	TP01.285
923:03 - 923:07	<p>922:14 THE WITNESS: Yes.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:18)</p>	TP01.286
924:14 - 924:20	<p>923:3 Q. All right. Mr. Prevoznik,</p> <p>923:4 Exhibit 40 is entitled "Draft DEA Comments</p> <p>923:5 From the 6-04-08 Meeting on Suspicious</p> <p>923:6 Orders." It's Bates number</p> <p>923:7 CAH_MDL2804_03234535.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:21)</p>	TP01.287
924:23 - 924:23	<p>924:14 Q. Okay. Would the DEA agree that</p> <p>924:15 in addition to completing a question --</p> <p>924:16 having a potential customer complete a</p> <p>924:17 questionnaire before a registrant agrees to</p> <p>924:18 ship them a controlled substance, that a</p> <p>924:19 registrant has to verify that the answers to</p> <p>924:20 that questionnaire are accurate and complete?</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:01)</p>	TP01.288
926:03 - 926:09	<p>924:23 THE WITNESS: Yes.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:13)</p>	TP01.289
	<p>926:3 Do you agree with that first</p> <p>926:4 underlined sentence, "DEA seemed to think the</p>	

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	926:5 thresholds focus principally on volumes, and 926:6 they express the view that an exclusive or 926:7 even principal focus on volumes is 926:8 inadequate"? 926:9 A. Yes.	
927:12 - 928:03	Prevoznik, Thomas 05-17-2019 (00:00:36)	TP01.290
	927:12 Q. -- "DEA did not object to our 927:13 recommendation that the particular drug or 927:14 drugs that cause an order to be an order of 927:15 interest or a suspicious order should not be 927:16 shipped but other drugs can be. Their point 927:17 was that in some circumstances the connection 927:18 between that drug and another drug in the 927:19 order should lead the wholesaler not to ship 927:20 the other drug as well. Again, in their 927:21 view, looking at a volume order drug by drug 927:22 is not enough, and basing thresholds solely 927:23 on volume is not enough. Even an order for a 927:24 drug that does not meet a volume threshold 927:25 may be suspicious in light of other aspects 928:1 of the order." 928:2 Does DEA agree with that 928:3 statement?	
928:06 - 928:06	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.291
	928:6 THE WITNESS: Yes.	
928:14 - 928:18	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.292
	928:14 Q. "DEA was emphatic that if there 928:15 were questions about an order, the order 928:16 should not be shipped." 928:17 Do you agree with that 928:18 statement?	
928:21 - 928:21	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.293
	928:21 THE WITNESS: Yes.	
929:13 - 929:16	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.294
	929:13 Does the DEA agree that 929:14 registrants should be reporting all 929:15 suspicious orders, even orders that aren't 929:16 shipped?	
929:20 - 930:01	Prevoznik, Thomas 05-17-2019 (00:00:14)	TP01.295
	929:20 THE WITNESS: Yes.	

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	929:21 QUESTIONS BY MS. SINGER: 929:22 Q. "Timeliness is very important. 929:23 DEA wants us to emphasize the need for rapid, 929:24 timely reporting." 929:25 Is that a point that DEA made 930:1 clear to registrants?	
930:06 - 930:08	Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.296
	930:6 THE WITNESS: It's also 930:7 regulation upon discovery, so it's 930:8 immediately upon discovery.	
930:10 - 930:11	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.297
	930:10 Q. So that's a yes? 930:11 A. Yes.	
933:20 - 933:23	Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.298
	933:20 Did the Rannazzisi letters, the 933:21 2006, 2007 letters, change the obligations of 933:22 registrants? 933:23 A. No.	
934:02 - 934:03	Prevoznik, Thomas 05-17-2019 (00:00:04)	TP01.299
	934:2 Q. Did they reflect a new policy 934:3 or interpretation by DEA?	
934:06 - 934:25	Prevoznik, Thomas 05-17-2019 (00:00:40)	TP01.300
	934:6 THE WITNESS: No, we were just 934:7 being more proactive to get the 934:8 registrants to see this was what was 934:9 going on. That's why we did the 934:10 distributor initiatives, to show them 934:11 with their own data, these are the 934:12 anomalies that we were seeing and 934:13 explaining to them this is what we 934:14 saw, and you should be paying 934:15 attention to these as well. 934:16 So the guidance letter -- or 934:17 not the guidance. The reiteration of 934:18 what their legal obligations were, 934:19 both statutorily and regulatory, were 934:20 in those letters, and it was to stop 934:21 what was going on at that time. 934:22 QUESTIONS BY MS. SINGER: 934:23 Q. And "stop" meaning the --	

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937:23 - 938:02	934:24 A. The diversion of controlled 934:25 substances into the illicit market. Prevoznik, Thomas 05-17-2019 (00:00:12)	TP01.301
938:10 - 938:10	937:23 Q. And do you think, does DEA 937:24 think, that the industry's failure to comply 937:25 with the Controlled Substances Act was due to 938:1 a failure to understand what the law required 938:2 of them? Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.302
942:04 - 942:08	938:10 THE WITNESS: No. Prevoznik, Thomas 05-17-2019 (00:00:12)	TP01.303
942:13 - 943:06	942:4 did the DEA, in the 942:5 Controlled Substances Act, make clear to 942:6 industry that the failure to prevent 942:7 diversion was a threat to public safety and 942:8 the public interest? Prevoznik, Thomas 05-17-2019 (00:00:41)	TP01.304
944:05 - 944:07	942:13 part of the registrant that is 942:14 applying to be a registrant 942:15 understands that they have to maintain 942:16 effective controls. They have to 942:17 follow the state laws. They have to 942:18 not be convicted of, you know, 942:19 felonies or anything like that. 942:20 But also they also know that 942:21 these drugs themselves are scheduled 942:22 controlled substances for a particular 942:23 reason, because they're addictive, 942:24 psychologically and physically they're 942:25 addictive, so they know that these 943:1 drugs have these properties within 943:2 themselves. 943:3 So they would understand that 943:4 these drugs are categorized or 943:5 scheduled in that manner because they 943:6 have the potential to hurt. Prevoznik, Thomas 05-17-2019 (00:00:10)	TP01.305
	944:5 Q. Okay. So would the DEA let a 944:6 registrant know if it was aware of problems 944:7 with its suspicious order monitoring system?	

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944:13 - 945:24	<p>Prevoznik, Thomas 05-17-2019 (00:01:16)</p> <p>944:13 THE WITNESS: So how I would 944:14 respond to this particular question is 944:15 when we sit down with a registrant and 944:16 they're explaining their system to us, 944:17 we are in a listening mode. We are 944:18 listening to what they say: "This is 944:19 what we're going to do. This is how 944:20 we're going to implement it. These 944:21 are the thresholds. These are the" -- 944:22 whatever. They're explaining the 944:23 system to us, so we listen to what 944:24 they're saying.</p> <p>944:25 If we, in listening to that, 945:1 they ask -- or we hear something that 945:2 doesn't sound quite right, we would 945:3 offer and say, "Well, you might want 945:4 to look at this."</p> <p>945:5 Sort of exactly like the 945:6 Rannazzisi letters in which we laid 945:7 out the foundation of these are the 945:8 things that we're seeing. We're 945:9 having trouble trying to figure out 945:10 why this is going on. So we're asking 945:11 you to ask the same questions of 945:12 yourselves of the data that you're 945:13 seeing.</p> <p>945:14 So what we're trying to do is 945:15 we're trying to put people in 945:16 compliance so that this stops, that 945:17 the diversion stops. So, yes, we 945:18 would -- we would offer suggestions to 945:19 them.</p> <p>945:20 However, if we're into an 945:21 investigation or something where it -- 945:22 where we are either investigating or 945:23 litigating, that might -- that 945:24 conversation might slow down.</p>	TP01.306
947:07 - 947:10	<p>Prevoznik, Thomas 05-17-2019 (00:00:08)</p> <p>947:7 Q. Okay. So you testified, too,</p>	TP01.307

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947:13 - 947:24	<p>947:8 that things can look good on paper or look 947:9 fine on paper, but what matters is how they 947:10 work in practice, correct?</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:25)</p> <p>947:13 THE WITNESS: Well, the 947:14 regulations require two things: 947:15 design and operate. So the design 947:16 would be this is what we propose, this 947:17 is what our system looks like, and 947:18 then becomes, well, what, in fact, did 947:19 you do with the operation of it.</p> <p>947:20 QUESTIONS BY MS. SINGER:</p> <p>947:21 Q. Okay. And you, the DEA, can't 947:22 always see what distributors don't do or do 947:23 wrong, especially if they're trying not to be 947:24 caught, correct?</p>	TP01.308
948:04 - 948:04	<p>Prevoznik, Thomas 05-17-2019 (00:00:01)</p>	TP01.309
948:08 - 948:13	<p>948:4 THE WITNESS: Correct.</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:17)</p> <p>948:8 Q. Okay. I want to turn to 948:9 Exhibit 42. 948:10 It is Exhibit Number 7 to the 948:11 Boggs deposition. It's called "American 948:12 Pain: The Largest US Pill Mill's Rise and 948:13 Fall."</p>	TP01.310
950:01 - 950:11	<p>Prevoznik, Thomas 05-17-2019 (00:00:19)</p> <p>950:1 Q. Okay. So it says here, "Gary 950:2 Boggs, special agent with the DEA's Office of 950:3 Diversion Control, says the cases that the 950:4 DEA has brought in recent years involved 950:5 wholesalers knowingly making enormous sales 950:6 to customers that were per se in violation of 950:7 DEA's rules."</p> <p>950:8 Do you see where I'm reading?</p> <p>950:9 A. Yes.</p> <p>950:10 Q. And does the DEA agree with 950:11 that statement?</p>	TP01.311
950:14 - 950:25	<p>Prevoznik, Thomas 05-17-2019 (00:00:22)</p> <p>950:14 THE WITNESS: Yes.</p> <p>950:15 QUESTIONS BY MS. SINGER:</p>	TP01.312

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950:16 - 950:25	950:16 Q. And then it goes on quoting 950:17 Mr. Boggs, "The notion put out by HDMA that 950:18 somehow or another the DEA is not providing 950:19 essential information to them is simply not 950:20 accurate, says Boggs. It's a smokescreen. 950:21 It's a step out of desperation." 950:22 Do you see that statement? 950:23 A. Yes. 950:24 Q. Okay. Do you agree with that 950:25 statement?	
951:05 - 951:05	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.313
951:18 - 951:20	951:5 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:13)	TP01.314
951:24 - 952:20	951:18 Q. All right. Exhibit 43, 951:19 Mr. Prevoznik. 951:20 This is MCKMDL00661483. Prevoznik, Thomas 05-17-2019 (00:00:55) 951:24 Q. All right. And this is an 951:25 e-mail Re: Report on House Energy and 952:1 Commerce Subcommittee Hearing on DEA and FDA 952:2 Transparency. 952:3 And I'll direct you to the 952:4 middle of the e-mail from Ann Berkey. 952:5 Do you see where I am? 952:6 A. Yes. 952:7 Q. Okay. And it's dated Tuesday, 952:8 April 8, 2014. 952:9 And if you look in the text of 952:10 that e-mail, it says, "I met today with Gary 952:11 Boggs, the new senior director of reg affairs 952:12 for US pharma for the east of the Mississippi 952:13 River, that is, who is based in Livonia. 952:14 He's a former top official with the DEA, and 952:15 we talked extensively about this bill, the 952:16 hearing, ways we can work with the Agency, et 952:17 cetera. He outlined in some detail the 952:18 processes that the DEA has had in place for 952:19 years to, quote, collaborate with wholesalers 952:20 in the way in which our industry, CAH" -- Prevoznik, Thomas 05-17-2019 (00:00:18)	TP01.315
953:17 - 953:23		TP01.316

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	953:17 Q. -- "has blown them off to the 953:18 point that the DEA is now hammering all of 953:19 us."	
	953:20 Does this accurately reflect 953:21 the sense of the -- is it true that the DEA 953:22 felt that the industry did not respond to 953:23 their guidance and request for compliance?	
954:07 - 954:07	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.317
	954:7 THE WITNESS: Yes.	
954:09 - 954:10	Prevoznik, Thomas 05-17-2019 (00:00:03)	TP01.318
	954:9 Q. And this is as of 2014, 954:10 correct?	
954:14 - 954:15	Prevoznik, Thomas 05-17-2019 (00:00:04)	TP01.319
	954:14 THE WITNESS: Yes, that's the 954:15 date on the e-mail.	
955:24 - 956:04	Prevoznik, Thomas 05-17-2019 (00:00:23)	TP01.320
	955:24 Okay. Exhibit 44. This is 955:25 ABDCMDL00139028.	
	956:1 It's called Summary of DEA HDMA 956:2 meeting, December 19, 2011.	
	956:3 Do you recall a meeting between 956:4 the DEA and HDMA in 2011?	
956:07 - 956:10	Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.321
	956:7 THE WITNESS: I don't. 956:8 QUESTIONS BY MS. SINGER:	
	956:9 Q. The DEA did meet with the HDMA 956:10 periodically, correct?	
956:13 - 957:01	Prevoznik, Thomas 05-17-2019 (00:00:22)	TP01.322
	956:13 THE WITNESS: Correct. 956:14 QUESTIONS BY MS. SINGER:	
	956:15 Q. Okay. And down at the bottom 956:16 of the page here, in the last paragraph, it 956:17 says, "HDMA asked if there was any -- if 956:18 there were any noncompliance trends 956:19 throughout the wholesale distribution 956:20 industry we should inform our members about."	
	956:21 Do you see where I am? 956:22 A. Yes. 956:23 Q. Okay. "Gary Boggs" -- 956:24 Who we talked about just a	

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	956:25 minute ago, correct?	
957:1 - 957:20	957:1 A. Yes. Prevoznik, Thomas 05-17-2019 (00:00:46) 957:4 Q. -- "the executive assistant to 957:5 the deputy administrator for diversion 957:6 control, led this response. He stated that 957:7 DEA's single greatest concern was their 957:8 belief that wholesaler distributors were lax 957:9 in analysis, review and acting on their own 957:10 ARCOS data. He stated that sometimes the 957:11 data were pretty egregious. He went on to 957:12 explain," turning the page, "that the Agency 957:13 had not seen changes in registrants' behavior 957:14 that it expected after presenting its 957:15 analysis of ARCOS data to them, so we have -- 957:16 quote, 'so we have upped our game.'" 957:17 Is this consistent with the 957:18 DEA's view and your testimony that 957:19 registrants were lax in their analysis, 957:20 review and acting on their own ARCOS data?	TP01.323
957:23 - 957:23	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.324
957:25 - 957:25	957:23 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:02)	TP01.325
958:04 - 958:04	957:25 Q. And was it pretty egregious? Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.326
958:06 - 958:08	958:4 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.327
958:12 - 958:18	958:6 Q. And when it says here that DEA 958:7 had "upped its game," do you know what that's 958:8 referring to? Prevoznik, Thomas 05-17-2019 (00:00:13)	TP01.328
	958:12 THE WITNESS: At this time 958:13 period, we were investigating and 958:14 litigating against the wholesalers.	
	958:15 QUESTIONS BY MS. SINGER: 958:16 Q. Okay. Prompted by DEA's sense 958:17 that that's what they needed to do given a 958:18 lack of voluntarily compliance, correct?	
958:22 - 958:22	Prevoznik, Thomas 05-17-2019 (00:00:01) 958:22 THE WITNESS: Yes.	TP01.329

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962:04 - 962:08	Prevoznik, Thomas 05-17-2019 (00:00:11) 962:4 Q. All right. In your testimony 962:5 on day one or day two, you were asked whether 962:6 suspicious orders always lead to diversion. 962:7 Do you remember? 962:8 A. Yes.	TP01.330
962:12 - 962:15	Prevoznik, Thomas 05-17-2019 (00:00:06) 962:12 Q. Okay. And I think your answer 962:13 to that was, no, it doesn't always lead to 962:14 diversion. 962:15 Does that seem right to you?	TP01.331
962:18 - 962:18	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.332
962:20 - 962:23	962:18 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:09) 962:20 Q. Okay. And is that because, 962:21 Mr. Prevoznik, not all suspicious orders turn 962:22 out to actually be suspicious? 962:23 A. Correct.	TP01.333
963:02 - 963:05	Prevoznik, Thomas 05-17-2019 (00:00:08) 963:2 Q. Okay. But if a distributor 963:3 doesn't investigate a suspicious order, it 963:4 wouldn't know whether that order was being 963:5 diverted, right?	TP01.334
963:08 - 963:08	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.335
963:10 - 963:16	963:8 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:17) 963:10 Q. And to use the language we 963:11 quoted earlier from the Diversion 963:12 Investigators Manual, sending out potentially 963:13 suspicious orders without investigating them 963:14 reflects a, quote, attitude of 963:15 irresponsibility. 963:16 Does DEA agree?	TP01.336
963:19 - 963:19	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.337
963:19 - 964:15	963:19 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:50) 963:23 Q. Let's turn to the Energy and 963:24 Commerce. Since we don't have previous -- 963:25 the exhibits from last time, we're going to 964:1 remark the Energy and Commerce report as	TP01.338

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	<p>964:2 Exhibit 46. It's the same report that went 964:3 in earlier in your testimony. 964:4 And industry lawyers asked 964:5 you -- they showed you a piece of the report 964:6 that said that DEA could have acted earlier. 964:7 Do you remember those 964:8 questions? 964:9 A. Vaguely, but, yes. 964:10 Q. Okay. And certainly this 964:11 Energy and Commerce report finds the DEA 964:12 could have done more than it did, correct? 964:13 A. Correct. 964:14 Q. Okay. But it's also highly 964:15 critical of distributors, is it not?</p>	
964:21 - 964:24	<p>Prevoznik, Thomas 05-17-2019 (00:00:06)</p> <p>964:21 THE WITNESS: Yes. 964:22 QUESTIONS BY MS. SINGER: 964:23 Q. Okay. And just for context, I 964:24 want to direct you to page 5 of the report.</p>	TP01.339
964:25 - 965:24	<p>Prevoznik, Thomas 05-17-2019 (00:01:02)</p> <p>964:25 On the bottom of the page, it 965:1 says in that last paragraph, "As the opioid 965:2 epidemic began to surge, the DEA, by 2005, 965:3 realized that traditional policing of 965:4 individual doctors and pharmacies was no 965:5 longer an effective approach against the 965:6 oncoming avalanche of opioids from rogue 965:7 Internet pharmacies and pill mills. Instead, 965:8 DEA's focus turned to the drug wholesale 965:9 distributors, a choke point in the 965:10 pharmaceutical supply chain, who transfer 965:11 drugs from manufacturers to businesses such 965:12 as clinics, hospitals and pharmacies where 965:13 they can be dispensed to patients. 965:14 Distributors in previous years had not 965:15 received enforcement attention from the DEA. 965:16 The new focus looked for greater impact for 965:17 the highly consolidated industry given the 965:18 three -- given that the three major drug 965:19 distributors - AmerisourceBergen, Cardinal</p>	TP01.340

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	965:20 Health and McKesson - control about 965:21 85 percent of the drug supply." 965:22 Do you agree with the statement 965:23 I've just read? 965:24 A. Yes.	
966:02 - 966:24	Prevoznik, Thomas 05-17-2019 (00:00:50) 966:2 Q. And then "Beginning in 2005, 966:3 the DEA undertook a series of initiatives 966:4 meant to educate wholesale drug distributors 966:5 about their legal obligations to prevent 966:6 controlled substance diversion. The DEA's 966:7 distributor initiative included one-on-one 966:8 meetings with wholesale distributors in which 966:9 DEA officials provided specific examples 966:10 regarding distributors' own customers whose 966:11 ordering habits were suggestive of trends 966:12 indicating the presence of diversion and 966:13 illicit Internet pharmacies. Of the five 966:14 distributors investigated by the committee, 966:15 AmerisourceBergen, Cardinal, HD Smith and 966:16 McKesson, each had one-on-one meetings with 966:17 DEA as part of this initiative. In addition, 966:18 during 2006 and 2007, the DEA sent a series 966:19 of three letters, sent to all DEA-registered 966:20 distributors outlining their legal 966:21 obligations to conduct due diligence and 966:22 report suspicious orders." 966:23 Is that also an accurate 966:24 statement of what happened?	TP01.341
967:02 - 967:02	Prevoznik, Thomas 05-17-2019 (00:00:01) 967:2 THE WITNESS: Yes.	TP01.342
967:04 - 967:13	Prevoznik, Thomas 05-17-2019 (00:00:20) 967:4 Q. "Apparently the DEA soon 967:5 realized that the largest distributors were 967:6 not taking their compliance requirements with 967:7 sufficient seriousness. In 2007 and 2008, 967:8 the DEA took enforcement action through legal 967:9 settlements against the three largest 967:10 wholesale distributors in the US for alleged 967:11 violations of the CSA, with multi-million	TP01.343

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967:17 - 968:19	<p>967:12 dollar fines involving two of them."</p> <p>967:13 Is that also accurate?</p> <p>Prevoznik, Thomas 05-17-2019 (00:01:16)</p> <p>967:17 THE WITNESS: Yes.</p> <p>967:18 QUESTIONS BY MS. SINGER:</p> <p>967:19 Q. Last paragraph. "Despite these</p> <p>967:20 settlement agreements and the subsequent</p> <p>967:21 policy enhancements that the three</p> <p>967:22 distributors made in their aftermath, the</p> <p>967:23 committee found that the distributors</p> <p>967:24 continued to ship large volumes of opioids</p> <p>967:25 into West Virginia. The three largest</p> <p>968:1 wholesale drug distributors in the United</p> <p>968:2 States - AmerisourceBergen, Cardinal Health</p> <p>968:3 and McKesson - sent more than 900 million</p> <p>968:4 doses of hydrocodone and oxycodone to West</p> <p>968:5 Virginia between 2005 and 2016. Cardinal</p> <p>968:6 Health was the largest supplier of controlled</p> <p>968:7 substances to West Virginia out of the five</p> <p>968:8 companies examined as part of the Committee's</p> <p>968:9 investigation, and distributed more than 366</p> <p>968:10 million doses of hydrocodone and oxycodone to</p> <p>968:11 West Virginia pharmacies between 2005 and</p> <p>968:12 2016. From April 2006 through 2016, McKesson</p> <p>968:13 supplied 299.87 million doses of hydrocodone</p> <p>968:14 and oxycodone to West Virginia pharmacies,</p> <p>968:15 AmerisourceBergen distributed 248.16 million</p> <p>968:16 doses of hydrocodone and oxycodone to West</p> <p>968:17 Virginia pharmacies between 2005 and 2016."</p> <p>968:18 Is that also consistent with</p> <p>968:19 DEA's understanding of what had occurred?</p>	TP01.344
968:22 - 968:22	<p>Prevoznik, Thomas 05-17-2019 (00:00:01)</p> <p>968:22 THE WITNESS: Yes.</p>	TP01.345
968:24 - 969:11	<p>Prevoznik, Thomas 05-17-2019 (00:00:25)</p> <p>968:24 Q. Turn the page, please. "Among</p> <p>968:25 the Committee's findings, distributors</p> <p>969:1 suffered a series of breakdowns or had a lack</p> <p>969:2 of follow-through in their -- through in</p> <p>969:3 their due diligence evaluations of</p> <p>969:4 prospective pharmacy customers. As</p>	TP01.346

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	969:5 demonstrated in the report, the committee 969:6 found instances of insufficient due diligence 969:7 by distributors who merely required 969:8 pharmacies to complete new customer 969:9 applications." 969:10 Now, we talked about that 969:11 earlier, correct?	
969:14 - 969:18	Prevoznik, Thomas 05-17-2019 (00:00:07) 969:14 THE WITNESS: Correct. 969:15 QUESTIONS BY MS. SINGER: 969:16 Q. And that is not sufficient to 969:17 comply with the registrant's obligation to 969:18 know their customers, correct?	TP01.347
969:23 - 969:23	Prevoznik, Thomas 05-17-2019 (00:00:01) 969:23 THE WITNESS: Correct.	TP01.348
969:25 - 970:09	Prevoznik, Thomas 05-17-2019 (00:00:18) 969:25 Q. "There were cases where data 970:1 submitted by a new customer was not 970:2 critically analyzed to identify any red flags 970:3 of controlled substance diversion, for 970:4 example, potential red flags regarding a 970:5 pharmacy's prescribing physicians that raised 970:6 concerns about possible diversion were not 970:7 questioned." 970:8 Is that consistent with DEA's 970:9 understanding of what occurred?	TP01.349
970:12 - 970:12	Prevoznik, Thomas 05-17-2019 (00:00:01) 970:12 THE WITNESS: Yes.	TP01.350
970:14 - 971:08	Prevoznik, Thomas 05-17-2019 (00:00:42) 970:14 Q. Goes on to say, "The 970:15 investigation found instances where there 970:16 were failures to monitor the volume of 970:17 controlled substances sold to customers. 970:18 Some distributors used thresholds to track 970:19 customers' purchases of controlled substances 970:20 and flag orders as suspicious when purchases 970:21 exceeded those limits. But some of these 970:22 thresholds were assigned arbitrarily and not 970:23 effective. Committee found instances in 970:24 which distributors set thresholds but failed	TP01.351

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970:25 to enforce them, assigned artificially high 971:1 hydrocodone threshold limits with little to 971:2 no documented justification, or continued to 971:3 raise threshold levels without thoroughly 971:4 investigating or documenting the 971:5 justifications presented by a customer 971:6 pharmacy." <p>971:7 Again, is that what DEA 971:8 observed happened during this time period?</p> <td>971:13 - 971:13 Prevoznik, Thomas 05-17-2019 (00:00:01)</td> <td>TP01.352</td>	971:13 - 971:13 Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.352
971:13 THE WITNESS: Yes.		
972:04 - 973:05 Prevoznik, Thomas 05-17-2019 (00:00:58)		TP01.353
972:4 Q. It goes on, "Despite efforts by 972:5 DEA to educate distributors about their 972:6 responsibility to report suspicious orders, 972:7 the companies reviewed by the committee 972:8 failed to address suspicious orders" -- I'm 972:9 sorry -- "suspicious order monitoring in 972:10 critical ways. Rather than reporting 972:11 individual suspicious orders as they were 972:12 identified, some distributors reported a 972:13 variety of other types of information to DEA 972:14 over the years. This information included 972:15 excessive orders encompassing drug shipments 972:16 that had already been shipped and suspicious 972:17 customers such as pharmacies with which 972:18 distributors had terminated business 972:19 relationships. Neither of these types of 972:20 reports informed DEA about suspicious orders 972:21 in realtime, nor did they guarantee the 972:22 suspicious orders reported to DEA were also 972:23 blocked by the distributors. The committee 972:24 also found that one distributor lacked any 972:25 formal order monitoring program. Rather, the 973:1 distributor's employees relied on subjective 973:2 criteria to investigate [sic] orders it 973:3 considered suspicious." <p>973:4 Does that also reflect what the 973:5 DEA knew to happen during this time period?</p>		
973:10 - 974:10 Prevoznik, Thomas 05-17-2019 (00:00:56)		TP01.354

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	<p>973:10 THE WITNESS: Yes.</p> <p>973:11 QUESTIONS BY MS. SINGER:</p> <p>973:12 Q. And the last paragraph.</p> <p>973:13 "Another critical failure identified by the</p> <p>973:14 Committee involved instances in which</p> <p>973:15 distributors appeared to turn a blind eye to</p> <p>973:16 red flags of possible drug diversion.</p> <p>973:17 Despite available information, distributors</p> <p>973:18 at times took only minimal steps to</p> <p>973:19 investigate possible warning signs of</p> <p>973:20 diversion and continued to ship controlled</p> <p>973:21 substances to suspect pharmacies. In several</p> <p>973:22 cases, distributors either failed to fully</p> <p>973:23 investigate potentially troubling information</p> <p>973:24 they obtained from customer pharmacies or</p> <p>973:25 willfully ignored it. These failures raise</p> <p>974:1 substantial concern given that DEA has said</p> <p>974:2 existing knowledge of a geographic area's</p> <p>974:3 problem with controlled substance abuse is a</p> <p>974:4 factor that distributors should take into</p> <p>974:5 account when evaluating customers."</p> <p>974:6 Now, is that true, that DEA had</p> <p>974:7 said knowledge of a geographic area's problem</p> <p>974:8 with controlled substance abuse is a factor</p> <p>974:9 that should be taken into account by</p> <p>974:10 registrants?</p>	
974:14 - 974:25	<p>Prevoznik, Thomas 05-17-2019 (00:00:22)</p> <p>974:14 THE WITNESS: Yes.</p> <p>974:15 QUESTIONS BY MS. SINGER:</p> <p>974:16 Q. Okay. "West Virginia has the</p> <p>974:17 highest drug overdose rate in the country,</p> <p>974:18 meaning distributors should have been</p> <p>974:19 particularly attuned to any red flags</p> <p>974:20 encountered when conducting due diligence on</p> <p>974:21 pharmacies in that state."</p> <p>974:22 Is that also an accurate</p> <p>974:23 reflection of a registrant's duty when</p> <p>974:24 shipping controlled substances into West</p> <p>974:25 Virginia or other hotspots?</p>	TP01.355
975:05 - 975:10	<p>Prevoznik, Thomas 05-17-2019 (00:00:09)</p>	TP01.356

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975:5 - 975:10	975:5 THE WITNESS: Yes. 975:6 QUESTIONS BY MS. SINGER: 975:7 Q. Okay. And this whole paragraph 975:8 that I just read, does that also reflect the 975:9 DEA's understanding of what happened during 975:10 this time period?	
975:16 - 975:16	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.357
975:16 - 979:07	975:16 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:38) 978:16 Q. Okay. Turning towards the 978:17 middle of the page, just below it, the second 978:18 paragraph from the bottom. "But as 978:19 demonstrated by the Committee's 978:20 investigation, the DEA did not always receive 978:21 the level of compliance required under the 978:22 CSA. The five distributors whose actions in 978:23 West Virginia were examined by the Committee 978:24 each had unique failures. The companies had 978:25 various policies and procedures in place to 979:1 prevent diversion but in some cases did not 979:2 adequately follow or carry out those 979:3 policies. As evidenced in the case studies 979:4 discussed in each section, distributors had 979:5 failings on multiple fronts." 979:6 Is that consistent with the 979:7 DEA's conclusions?	TP01.358
979:12 - 979:25	Prevoznik, Thomas 05-17-2019 (00:00:26) 979:12 THE WITNESS: Yes. 979:13 QUESTIONS BY MS. SINGER: 979:14 Q. "For instance, it is not 979:15 sufficient due diligence for a distributor to 979:16 only require prospective or existing 979:17 customers to complete pharmacy questionnaires 979:18 or supply supplemental data. The information 979:19 disclosed on such questionnaires or the data 979:20 submitted must also be critically analyzed to 979:21 identify any red flags of controlled 979:22 substance diversion." 979:23 Does that accurately reflect a 979:24 distributor's obligations or a registrant's	TP01.359

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980:03 - 980:10	979:25 obligations? Prevoznik, Thomas 05-17-2019 (00:00:10)	TP01.360
	980:3 THE WITNESS: Yes.	
	980:4 QUESTIONS BY MS. SINGER:	
	980:5 Q. "Once distributors bring	
	980:6 pharmacies on board, they need to monitor the	
	980:7 volume of controlled substances sold to	
	980:8 customers."	
	980:9 Does that also accurately	
	980:10 reflect a registrant's duties?	
980:13 - 980:23	Prevoznik, Thomas 05-17-2019 (00:00:16)	TP01.361
	980:13 THE WITNESS: Yes.	
	980:14 QUESTIONS BY MS. SINGER:	
	980:15 Q. And the last sentence,	
	980:16 "Subsequently, when distributors set	
	980:17 thresholds for customers, they should be	
	980:18 enforced. In such cases where thresholds are	
	980:19 adjusted, distributors should be able to	
	980:20 document the justification for these	
	980:21 changes."	
	980:22 Does that also accurately	
	980:23 reflect a registrant's obligations?	
981:02 - 981:02	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.362
	981:2 THE WITNESS: Yes.	
981:15 - 982:01	Prevoznik, Thomas 05-17-2019 (00:00:32)	TP01.363
	981:15 (Prevoznik Plaintiff's Exhibit	
	981:16 P47 marked for identification.)	
	981:17 QUESTIONS BY MS. SINGER:	
	981:18 Q. Okay. So I want to turn to	
	981:19 Exhibit 47, please.	
	981:20 And that is Bates number	
	981:21 PPLP0300001799742.	
	981:22 If you turn to the first slide,	
	981:23 it's titled "DEA/OD 11th Pharmaceutical	
	981:24 Industry Conference."	
	981:25 Do you recognize this	
	982:1 presentation?	
982:15 - 982:20	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.364
	982:15 Q. Okay. It does have on the	
	982:16 front page DOJ, DEA logos, correct?	

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982:17 - 983:19	<p>982:17 A. Yes.</p> <p>982:18 Q. Okay. And does it look -- from</p> <p>982:19 your knowledge, is this a presentation by the</p> <p>982:20 DEA?</p> <p>Prevoznik, Thomas 05-17-2019 (00:00:44)</p> <p>982:23 THE WITNESS: Yes.</p> <p>982:24 QUESTIONS BY MS. SINGER:</p> <p>982:25 Q. Okay. And if you turn to the</p> <p>983:1 fifth page, with the slide "retail</p> <p>983:2 diversion," 90 percent at doctor, pharmacy,</p> <p>983:3 hospital levels.</p> <p>983:4 Do you see that slide?</p> <p>983:5 A. Yes.</p> <p>983:6 Q. Okay. And if you look at the</p> <p>983:7 notes that are at the bottom of that slide,</p> <p>983:8 do you see the bottom section that starts,</p> <p>983:9 "Estimated 1.5 percent of doctors are</p> <p>983:10 negligent and/or dishonest"?</p> <p>983:11 Do you see where I'm reading?</p> <p>983:12 A. Yes.</p> <p>983:13 Q. Okay. It says, "That portion</p> <p>983:14 of DEA-registered physicians is many</p> <p>983:15 thousands. Their CS, or controlled</p> <p>983:16 substance, prescribing would total hundreds</p> <p>983:17 of thousands of scripts/millions of dosage</p> <p>983:18 units into illicit market."</p> <p>983:19 Is that accurate?</p>	TP01.365
983:25 - 984:05	<p>Prevoznik, Thomas 05-17-2019 (00:00:09)</p> <p>983:25 THE WITNESS: Yes.</p> <p>984:1 QUESTIONS BY MS. SINGER:</p> <p>984:2 Q. And is it true, as it says</p> <p>984:3 here, that it is impossible for DEA to</p> <p>984:4 investigate and discipline that number of</p> <p>984:5 professionals?</p>	TP01.366
984:09 - 984:13	<p>Prevoznik, Thomas 05-17-2019 (00:00:05)</p> <p>984:9 THE WITNESS: I mean, we do the</p> <p>984:10 best we can.</p> <p>984:11 QUESTIONS BY MS. SINGER:</p> <p>984:12 Q. But that's a lot of --</p> <p>984:13 A. It's a lot.</p>	TP01.367

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984:17 - 984:22	Prevoznik, Thomas 05-17-2019 (00:00:15) 984:17 Q. And the last line here, "Far 984:18 more effective, address the risk at the apex 984:19 of the distribution center [sic]." 984:20 Is that accurate, that that is 984:21 a more effective way of enforcing compliance 984:22 with the Controlled Substances Act?	TP01.368
985:02 - 985:03	Prevoznik, Thomas 05-17-2019 (00:00:02) 985:2 Q. Or an important tool for the 985:3 DEA?	TP01.369
985:06 - 985:12	Prevoznik, Thomas 05-17-2019 (00:00:16) 985:6 THE WITNESS: Yes. 985:7 QUESTIONS BY MS. SINGER: 985:8 Q. Okay. And in fact, that's part 985:9 of the foundation of the Controlled 985:10 Substances Act, that each participant in the 985:11 supply chain has to police its own 985:12 participation in that supply chain, correct?	TP01.370
985:16 - 985:16	Prevoznik, Thomas 05-17-2019 (00:00:01) 985:16 THE WITNESS: Yes.	TP01.371
986:09 - 987:07	Prevoznik, Thomas 05-17-2019 (00:00:55) 986:9 All right. I'm showing you 986:10 Exhibit 48. And the level -- and I'm sorry, 986:11 this is CAH_MDL2804_00889528. 986:12 Do you recognize the logo on 986:13 the front of this presentation? 986:14 A. Yes. 986:15 Q. And what is it? 986:16 A. It's our Chief Counsel's logo. 986:17 Q. Okay. And if you turn to the 986:18 inside first page, How to Keep Or Lose Your 986:19 DEA Registration, do you recognize this 986:20 presentation? 986:21 A. Yes. 986:22 Q. And what do you recognize it to 986:23 be? 986:24 A. It was one of the -- it was -- 986:25 it was given at a conference that we held. 987:1 Q. A conference -- 987:2 A. For the industry.	TP01.372

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	987:3 Q. Okay. A conference that DEA 987:4 had for industry? 987:5 A. Yes. 987:6 Q. And do you know who gave this 987:7 presentation?	
987:08 - 987:09	Prevoznik, Thomas 05-17-2019 (00:00:02)	TP01.373
	987:8 Do you know if would have been 987:9 Linden Barber?	
987:12 - 988:06	Prevoznik, Thomas 05-17-2019 (00:00:36)	TP01.374
	987:12 THE WITNESS: I believe it was 987:13 Linden that gave this. 987:14 QUESTIONS BY MS. SINGER: 987:15 Q. Okay. And Linden Barber was 987:16 with the Chief Counsel's Office of DEA, 987:17 correct? 987:18 A. Yes. 987:19 Q. Okay. And if you turn to 987:20 page 4 of the presentation, titled "Effective 987:21 Controls Against Diversion," the first point 987:22 there is what, the first bullet point? 987:23 A. "Good recordkeeping is 987:24 essential." 987:25 Q. Do you agree with that 988:1 statement? 988:2 A. Yes. 988:3 Q. In DEA's experience, is the 988:4 absence of documentation a fairly good 988:5 indication that something didn't happen in a 988:6 registrant's compliance program?	
988:09 - 988:09	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.375
	988:9 THE WITNESS: Yes.	
988:11 - 988:20	Prevoznik, Thomas 05-17-2019 (00:00:24)	TP01.376
	988:11 Q. Okay. Turning to page 9, this 988:12 is what doesn't work, or how to lose your DEA 988:13 registration. 988:14 The second bullet point, what 988:15 does that say? 988:16 A. "It is not my job to 988:17 second-guess the doctor." 988:18 Q. Okay. And that's not an excuse	

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988:19 that the DEA will accept from a registrant, 988:20 correct?		
988:23 - 989:03	Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.377
988:23 THE WITNESS: Yes. 988:24 QUESTIONS BY MS. SINGER: 988:25 Q. And that's because it's a 989:1 registrant's responsibility to act on 989:2 information that points to diversion, 989:3 correct?		
989:06 - 989:12	Prevoznik, Thomas 05-17-2019 (00:00:15)	TP01.378
989:6 THE WITNESS: Correct. 989:7 QUESTIONS BY MS. SINGER: 989:8 Q. And it's not that the 989:9 registrant is being asked to judge a 989:10 prescription or a patient, but to look at red 989:11 flags like the volume or dose or appearance 989:12 of a practice, et cetera, correct?		
989:16 - 989:24	Prevoznik, Thomas 05-17-2019 (00:00:14)	TP01.379
989:16 THE WITNESS: Yes, they should 989:17 look into totality of everything 989:18 that's presented to them. 989:19 QUESTIONS BY MS. SINGER: 989:20 Q. Okay. And the last excuse on 989:21 this slide, "I'm not responsible for what my 989:22 customer does with the drugs." 989:23 Is that an excuse that the DEA 989:24 accepts from a registrant?		
990:02 - 990:06	Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.380
990:2 THE WITNESS: No. 990:3 QUESTIONS BY MS. SINGER: 990:4 Q. And that's because a registrant 990:5 is responsible to make sure that they are not 990:6 supplying to potential diversion, correct?		
990:10 - 990:10	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.381
990:10 THE WITNESS: Correct.		
992:08 - 992:23	Prevoznik, Thomas 05-17-2019 (00:00:32)	TP01.382
992:8 Q. Okay. And then it goes on to 992:9 say, "Know your customers and, where 992:10 applicable, the prescriber's business or 992:11 professional practice."		

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Page/Line	Source	ID
992:12 - 992:23	992:12 Is that also the DEA's guidance 992:13 to industry as to what's required? 992:14 A. Yes. 992:15 Q. And "know the statutory 992:16 factors, the DEA's final orders," and then 992:17 lastly, "act consistently with DEA's goal: 992:18 protect the public health and safety from the 992:19 harms caused by diversion." 992:20 Is that also the guidance that 992:21 DEA gave to industry about complying with the 992:22 Controlled Substances Act? 992:23 A. Yes.	
992:25 - 993:01	Prevoznik, Thomas 05-17-2019 (00:00:00)	TP01.383
	992:25 (Prevoznik Plaintiff's Exhibit 993:1 P49 marked for identification.)	
997:14 - 997:16	Prevoznik, Thomas 05-17-2019 (00:00:06)	TP01.384
	997:14 Q. Would DEA agree that a 997:15 significant increase in a prescriber's volume 997:16 is a sign of potential diversion?	
997:19 - 997:24	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.385
	997:19 THE WITNESS: Just volume 997:20 alone? 997:21 QUESTIONS BY MS. SINGER: 997:22 Q. That it is one sign of 997:23 potential diversion, yes. 997:24 A. It --	
998:02 - 998:08	Prevoznik, Thomas 05-17-2019 (00:00:12)	TP01.386
	998:2 THE WITNESS: Potentially, yes. 998:3 QUESTIONS BY MS. SINGER: 998:4 Q. Okay. And that a prescriber 998:5 who is prescribing at very high volume 998:6 relative to other practitioners, that would 998:7 also be another potential red flag of 998:8 diversion, correct?	
998:13 - 998:24	Prevoznik, Thomas 05-17-2019 (00:00:16)	TP01.387
	998:13 THE WITNESS: It could be. It 998:14 just depends on what is the 998:15 physician's practice; does he 998:16 specialize in end of life or something 998:17 like that. I mean, you'd have to take	

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	998:18 in other factors. 998:19 QUESTIONS BY MS. SINGER: 998:20 Q. Right. You have to look at the 998:21 whole picture. 998:22 But that's one sign that might 998:23 alert you to take a closer look, correct? 998:24 A. Correct.	
999:03 - 999:07	Prevoznik, Thomas 05-17-2019 (00:00:13)	TP01.388
	999:3 Q. And if the prescriber is 999:4 prescribing at very high doses, again, one 999:5 factor, depending on their specialty and 999:6 patients, that might alert a registrant to 999:7 potential diversion, correct?	
999:12 - 999:12	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.389
	999:12 THE WITNESS: Correct.	
999:25 - 1000:04	Prevoznik, Thomas 05-17-2019 (00:00:10)	TP01.390
	999:25 Q. These are the kinds of 1000:1 commonsense red flags that a registrant 1000:2 should know to apply in looking for diversion 1000:3 without the DEA telling them specifically to 1000:4 look for them, correct?	
1000:06 - 1000:06	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.391
	1000:6 THE WITNESS: Yes.	
1007:11 - 1007:17	Prevoznik, Thomas 05-17-2019 (00:00:19)	TP01.392
	1007:11 Q. Now, does the fact that there 1007:12 are bad doctors who are writing illegitimate 1007:13 prescriptions or pharmacies that are 1007:14 dispensing illegally relieve distributors or 1007:15 manufacturers of their duty to review their 1007:16 own information and data for suspicious 1007:17 orders and signs of diversion?	
1007:24 - 1007:24	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.393
	1007:24 THE WITNESS: No.	
1008:02 - 1008:06	Prevoznik, Thomas 05-17-2019 (00:00:10)	TP01.394
	1008:2 Q. And in fact, in a closed 1008:3 system, the participants in the supply chain, 1008:4 those who are on the inside, have a duty to 1008:5 look out for bad doctors and bad pharmacies, 1008:6 correct?	
1008:10 - 1008:10	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.395

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	1008:10 THE WITNESS: Yes.	
1010:01 - 1010:09	Prevoznik, Thomas 05-17-2019 (00:00:22)	TP01.465
1010:1	Q. Now, you talked about the fact	
1010:2	1010:2 that DEA doesn't set a formula or a threshold	
1010:3	1010:3 for industry to apply, correct?	
1010:4	A. Correct.	
1010:5	Q. And is that -- is the reason	
1010:6	1010:6 for that because the DEA wouldn't necessarily	
1010:7	1010:7 be able to capture what the industry knows	
1010:8	1010:8 about its own customers in setting a	
1010:9	1010:9 threshold?	
1010:12 - 1011:02	Prevoznik, Thomas 05-17-2019 (00:00:34)	TP01.466
1010:12	1010:12 THE WITNESS: I think it's	
1010:13	1010:13 part -- a part of -- certainly that's	
1010:14	1010:14 part of it, but the other part would	
1010:15	1010:15 also be we don't regulate the practice	
1010:16	1010:16 of medicine, so we're not interfering	
1010:17	1010:17 with what doctors are doing to treat	
1010:18	1010:18 their patients.	
1010:19	1010:19 So in discussions with -- when	
1010:20	1010:20 these thresholds and things -- it also	
1010:21	1010:21 affects the opposite side. So it's	
1010:22	1010:22 not only the diverted side, but it's	
1010:23	1010:23 also legitimate patients who can't get	
1010:24	1010:24 them because of these thresholds that	
1010:25	1010:25 are in place. So it's affecting both	
1011:1	1011:1 sides of the -- it's a delicate	
1011:2	1011:2 balance.	
1011:11 - 1011:14	Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.396
1011:11	1011:11 Q. Okay. And the danger is if the	
1011:12	1011:12 DEA were to set the threshold too high, it	
1011:13	1011:13 wouldn't be a real check on identifying	
1011:14	1011:14 suspicious orders, correct?	
1011:18 - 1011:22	Prevoznik, Thomas 05-17-2019 (00:00:06)	TP01.397
1011:18	1011:18 THE WITNESS: Yes.	
1011:19	1011:19 QUESTIONS BY MS. SINGER:	
1011:20	1011:20 Q. And if you set it too low, as	
1011:21	1011:21 you said, patients might not be able to get	
1011:22	1011:22 medicine they need, correct?	
1012:01 - 1012:01	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.398

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1012:03 - 1012:07	1012:1 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:14)	TP01.399
	1012:3 Q. And so it's not that the DEA 1012:4 has some answer on what the threshold should 1012:5 be and isn't telling industry; it's that the 1012:6 DEA is actually saying that industry knows 1012:7 better from its own customers, correct?	
1012:10 - 1012:11	Prevoznik, Thomas 05-17-2019 (00:00:02)	TP01.400
	1012:10 THE WITNESS: They're in a 1012:11 better position than we are.	
1012:15 - 1012:16	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.401
	1012:15 Q. Okay. So let's go to -- I'm 1012:16 showing you Exhibit 54.	
1012:17 - 1014:01	Prevoznik, Thomas 05-17-2019 (00:01:19)	TP01.402
	1012:17 So do you recognize 1012:18 MNK-T1_0008504654? 1012:19 A. I recognize the names. 1012:20 Q. Okay. Which names do you 1012:21 recognize? 1012:22 A. Mark Caverly and James 1012:23 Crawford. 1012:24 Q. And who are they? 1012:25 A. Former employees of DEA. 1013:1 Q. Okay. And it says -- if you 1013:2 look down this document, you see 1013:3 Mr. Crawford, I think, three paragraphs from 1013:4 the bottom. Okay. I'm sorry, let's go up 1013:5 from that to the question. 1013:6 "During the distributor 1013:7 breakout session, suspicious order monitoring 1013:8 was certainly a hotbed of discussion. Are 1013:9 there any plans for DEA to publicize 1013:10 information to implement SOM, or suspicious 1013:11 order monitoring, incorporate algorithms 1013:12 where products are more likely to be 1013:13 diverted?" 1013:14 Do you see where I'm reading? 1013:15 A. Yes. 1013:16 Q. Okay. And then can you read 1013:17 Mr. Crawford's response?	

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1013:18 - 1014:22	A. "Whatever we put out will be outdated by the time we put it out. You're looking at a number. Tell me how much -- tell me how much that we can't exceed. DEA can't do that. It's part of your due diligence, knowing your customer."	
1013:24 - 1014:1	Q. And does that reflect what you just testified to in the guidance that DEA gave industry?	
1014:02 - 1014:02	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.403
1014:2	A. Yes.	
1015:03 - 1015:10	Prevoznik, Thomas 05-17-2019 (00:00:23)	TP01.404
1015:3 - 1015:10	Q. Okay. Showing you Exhibit 55. My goal here is to make your pile go up and mine go down. All right. This is MCKMDL00561303, executive summary regarding the HDMA document. Have you seen this document before, Mr. Prevoznik?	
1015:11 - 1015:23	Prevoznik, Thomas 05-17-2019 (00:00:35)	TP01.405
1015:11 - 1015:21	A. I'm not sure. Q. Okay. Let me direct you to the last page, Bates number 306. It says in that top bullet to question 10, "This is another area that we have made great strides in over the past few years. Our analytical capabilities provide us with greater insight into our own customer base. We have this data already and frankly are in a position to provide better information to DEA than they could provide to us."	
1015:22 - 1015:23	Does DEA agree with that statement?	
1016:01 - 1016:06	Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.406
1016:1	THE WITNESS: Yes.	
1016:2	QUESTIONS BY MS. SINGER:	
1016:3 - 1016:5	Q. And it says as a sidenote, "DEA does not have dispensing data, nor do they have noncontrol data," correct?	

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1017:01 - 1017:07	1016:6 A. Correct. Prevoznik, Thomas 05-17-2019 (00:00:23)	TP01.407
	1017:1 Q. Based on your experience 1017:2 in all of your years at DEA in management and 1017:3 as a diversion investigator and as the 1017:4 representative of the DEA here today, did DEA 1017:5 make the best judgments it could at the time 1017:6 to use your authority and resources most 1017:7 effectively to prevent diversion?	
1017:13 - 1017:14	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.408
	1017:13 THE WITNESS: Yes, I think we 1017:14 did.	
1017:16 - 1017:20	Prevoznik, Thomas 05-17-2019 (00:00:13)	TP01.409
	1017:16 Q. Had distributors reported 1017:17 suspicious orders to the DEA as the law 1017:18 required would DEA have been able to use its 1017:19 resources more effectively to identify and 1017:20 prevent diversion?	
1018:03 - 1018:03	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.410
	1018:3 THE WITNESS: I believe so.	
1018:11 - 1018:14	Prevoznik, Thomas 05-17-2019 (00:00:14)	TP01.411
	1018:11 Q. Okay. And if registrants had 1018:12 reported suspicious orders to the DEA, does 1018:13 the DEA believe that there would have been 1018:14 less diversion, less abuse and less death?	
1018:21 - 1018:21	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.412
	1018:21 THE WITNESS: Yes.	
1022:13 - 1022:21	Prevoznik, Thomas 05-17-2019 (00:00:36)	TP01.413
	1022:13 Q. I'm going to show you 1022:14 Exhibit 56. 1022:15 Mr. Prevoznik, this is our 1022:16 effort to put in a timeline the actions DEA 1022:17 took against defendants in this litigation. 1022:18 Does this capture the major 1022:19 enforcement initiatives that DEA took against 1022:20 distributors, manufacturers and distributors, 1022:21 including pharmacies?	
1025:24 - 1026:06	Prevoznik, Thomas 05-17-2019 (00:00:29)	TP01.414
	1025:24 THE WITNESS: Yeah. 1025:25 It appears to have most of the	

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	1026:1 highlights. 1026:2 QUESTIONS BY MS. SINGER: 1026:3 Q. Okay. And is it fair to say 1026:4 that the DEA has investigated or taken action 1026:5 against virtually every major distributor of 1026:6 opioids over the last 15 years?	
1026:09 - 1026:09	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.415
	1026:9 THE WITNESS: Yes.	
1026:12 - 1026:13	Prevoznik, Thomas 05-17-2019 (00:00:04)	TP01.467
	1026:12 Q. And also the major pharmacy 1026:13 chains that distribute opioids?	
1026:15 - 1026:18	Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.468
	1026:15 THE WITNESS: Yes. 1026:16 QUESTIONS BY MS. SINGER: 1026:17 Q. And also manufacturers like 1026:18 Mallinckrodt and Purdue, correct?	
1026:20 - 1026:24	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.469
	1026:20 THE WITNESS: Correct. 1026:21 QUESTIONS BY MS. SINGER: 1026:22 Q. Now, this chart doesn't reflect 1026:23 additional actions that the DEA took against 1026:24 doctors and pharmacists, correct?	
1027:03 - 1027:09	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.470
	1027:3 THE WITNESS: Yes. 1027:4 QUESTIONS BY MS. SINGER: 1027:5 Q. Or actions you took against 1027:6 independent pharmacies. 1027:7 And I take it the DEA also took 1027:8 enforcement action against non-chain 1027:9 pharmacies, correct?	
1027:17 - 1027:22	Prevoznik, Thomas 05-17-2019 (00:00:08)	TP01.471
	1027:17 THE WITNESS: Yes. In my 1027:18 personal capacity, yes, we would. 1027:19 QUESTIONS BY MS. SINGER: 1027:20 Q. Okay. So this isn't everything 1027:21 the DEA did in this time period, correct? 1027:22 A. Correct.	
1028:05 - 1028:08	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.416
	1028:5 Q. Okay. Now, isn't it true that 1028:6 even without information on a competitor's	

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1028:11 - 1028:25	<p>1028:7 orders, that registrants can identify 1028:8 suspicious orders and potential diversion? Prevoznik, Thomas 05-17-2019 (00:00:20)</p>	TP01.417
	<p>1028:11 THE WITNESS: So essentially 1028:12 their own data. 1028:13 QUESTIONS BY MS. SINGER: 1028:14 Q. Yes. 1028:15 A. Yes. 1028:16 Q. Okay. And when you've taken -- 1028:17 when you, the DEA, has taken enforcement 1028:18 actions or entered into settlement agreements 1028:19 with registrants, you've looked at their own 1028:20 data, correct? 1028:21 A. Yes. 1028:22 Q. And what those registrants 1028:23 should have known or did know about their own 1028:24 customers, correct? 1028:25 A. Correct.</p>	
1029:04 - 1029:06	Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.418
	<p>1029:4 Q. And you haven't taken those 1029:5 actions based on data from other registrants, 1029:6 correct?</p>	
1029:09 - 1029:09	Prevoznik, Thomas 05-17-2019 (00:00:00)	TP01.419
	<p>1029:9 THE WITNESS: Correct.</p>	
1029:12 - 1029:16	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.420
	<p>1029:12 So just to be perfectly clear, 1029:13 you didn't expect Cardinal to know what 1029:14 McKesson or AmerisourceBergen was supplying 1029:15 to a customer, correct? 1029:16 A. Correct.</p>	
1029:19 - 1029:23	Prevoznik, Thomas 05-17-2019 (00:00:10)	TP01.421
	<p>1029:19 Q. Is it the DEA's experience that 1029:20 suspicious orders filled by manufacturers, 1029:21 distributors and pharmacies were suspicious 1029:22 in their own right without anybody else's 1029:23 data?</p>	
1030:03 - 1030:08	Prevoznik, Thomas 05-17-2019 (00:00:10)	TP01.422
	<p>1030:3 THE WITNESS: Yes. 1030:4 QUESTIONS BY MS. SINGER: 1030:5 Q. And when distributors take on</p>	

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1030:11 - 1030:11	1030:6 or registrants take on a new customer, DEA 1030:7 recommends that they ask whether that 1030:8 customer uses other distributors, correct? Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.423
1030:18 - 1030:21	1030:11 THE WITNESS: Yes. Prevoznik, Thomas 05-17-2019 (00:00:07) 1030:18 DEA also recommends that a 1030:19 distributor obtain dispensing data from a 1030:20 pharmacy before they take them on as a 1030:21 customer, correct?	TP01.424
1030:24 - 1030:25	1030:24 THE WITNESS: Yes, if they can 1030:25 get it.	TP01.425
1032:15 - 1032:19	1032:15 Q. Now, if a pharmacy won't 1032:16 provide dispensing information to a 1032:17 distributor, would that be a red flag that 1032:18 the distributor needs to look more closely at 1032:19 that customer?	TP01.426
1033:03 - 1033:04	1033:3 THE WITNESS: Yes, they should 1033:4 be.	TP01.427
1033:08 - 1033:09	1033:8 Q. A distributor should ask? 1033:9 A. Should ask for it.	TP01.428
1034:04 - 1034:07	1034:4 Q. Now, distributors have 1034:5 information on both controlled and 1034:6 noncontrolled substances that are ordered by 1034:7 a customer, correct?	TP01.429
1034:10 - 1034:10	1034:10 THE WITNESS: Yes.	TP01.430
1034:12 - 1034:15	1034:12 Q. And that lets them see where a 1034:13 customer's order of controlled substances is 1034:14 disproportionate to its other orders, 1034:15 correct?	TP01.431
1034:19 - 1034:19	1034:19 THE WITNESS: Yes.	TP01.432
1034:21 - 1034:25	Prevoznik, Thomas 05-17-2019 (00:00:11)	TP01.433

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	1034:21 Q. And so if a customer is 1034:22 ordering a lot of opioids and very little 1034:23 antibiotics or diabetes medicine, that would 1034:24 be one potential red flag of diversion, 1034:25 correct?	
1035:04 - 1035:13	Prevoznik, Thomas 05-17-2019 (00:00:16) 1035:4 THE WITNESS: Yes, it could 1035:5 potentially be a red flag. 1035:6 QUESTIONS BY MS. SINGER: 1035:7 Q. A red flag? 1035:8 A. Yes. 1035:9 Q. Okay. And it's also true that 1035:10 pharmacies that order a certain mix of drugs 1035:11 that are abused together, that that can be 1035:12 another red flag of potential diversion, 1035:13 correct?	TP01.434
1035:17 - 1035:21	Prevoznik, Thomas 05-17-2019 (00:00:08) 1035:17 THE WITNESS: Yes. 1035:18 QUESTIONS BY MS. SINGER: 1035:19 Q. Now, distributors have that 1035:20 data on other noncontrolled substance orders, 1035:21 correct?	TP01.435
1036:01 - 1036:06	Prevoznik, Thomas 05-17-2019 (00:00:11) 1036:1 THE WITNESS: Yes. 1036:2 QUESTIONS BY MS. SINGER: 1036:3 Q. But DEA doesn't get reporting 1036:4 from distributors on noncontrolled substances 1036:5 ordered by customers, correct? 1036:6 A. No, we do not.	TP01.436
1037:09 - 1037:10	Prevoznik, Thomas 05-17-2019 (00:00:04) 1037:9 Q. And DEA doesn't have 1037:10 prescribing information in ARCOS, correct?	TP01.437
1037:13 - 1037:17	Prevoznik, Thomas 05-17-2019 (00:00:06) 1037:13 THE WITNESS: Correct. 1037:14 QUESTIONS BY MS. SINGER: 1037:15 Q. But that information is 1037:16 certainly useful in detecting suspicious 1037:17 orders or potential diversion, correct?	TP01.438
1037:20 - 1037:25	Prevoznik, Thomas 05-17-2019 (00:00:11) 1037:20 THE WITNESS: Correct.	TP01.439

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	1037:21 QUESTIONS BY MS. SINGER: 1037:22 Q. Is DEA aware that registrants 1037:23 have information -- have access to 1037:24 information on cash payments that are 1037:25 received by pharmacies?	
1038:05 - 1038:11	Prevoznik, Thomas 05-17-2019 (00:00:05) 1038:5 THE WITNESS: I believe we do. 1038:6 I believe they do. 1038:7 QUESTIONS BY MS. SINGER: 1038:8 Q. They do? 1038:9 A. Yeah. 1038:10 Q. And does DEA have that 1038:11 information?	TP01.440
1038:13 - 1039:05	Prevoznik, Thomas 05-17-2019 (00:00:32) 1038:13 THE WITNESS: If we subpoena 1038:14 it. 1038:15 QUESTIONS BY MS. SINGER: 1038:16 Q. Okay. But not in the regular 1038:17 course -- 1038:18 A. No. 1038:19 Q. -- of identifying potential 1038:20 diversion? 1038:21 A. Right. 1038:22 Q. Now, does ARCOS data tell you 1038:23 whether a customer is near a hospital or a 1038:24 cancer center or a hospice treatment 1038:25 facility? 1039:1 A. No, it's just transactional 1039:2 data. 1039:3 Q. Okay. But distributors and 1039:4 manufacturers would learn that information in 1039:5 their due diligence on customers, correct?	TP01.441
1039:08 - 1039:08	Prevoznik, Thomas 05-17-2019 (00:00:01) 1039:8 THE WITNESS: Yes.	TP01.442
1039:22 - 1040:02	Prevoznik, Thomas 05-17-2019 (00:00:11) 1039:22 Q. So when you get, you know, a 1039:23 big stack of excess order reports or 1039:24 ingredient limit reports, you can't tell if a 1039:25 large order is from a customer that's near an 1040:1 oncology center or a hospital, for instance,	TP01.443

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1040:05 - 1040:06	1040:2 correct? Prevoznik, Thomas 05-17-2019 (00:00:02)	TP01.444
	1040:5 THE WITNESS: Correct. From 1040:6 the reports, you cannot.	
1043:02 - 1043:05	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.445
	1043:2 Q. And is it the DEA's experience 1043:3 that registrants have objected to sharing 1043:4 ARCOS data with their competitors?	
	1043:5 A. Yes.	
1045:07 - 1045:11	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.446
	1045:7 Q. And if a registrant has 1045:8 information that would alert it to diversion, 1045:9 it has an obligation under the Controlled 1045:10 Substances Act to use that information to 1045:11 prevent diversion, correct?	
1045:14 - 1045:17	Prevoznik, Thomas 05-17-2019 (00:00:04)	TP01.447
	1045:14 THE WITNESS: Correct. 1045:15 QUESTIONS BY MS. SINGER:	
	1045:16 Q. And you can't be like that 1045:17 monkey, hiding your eyes --	
1045:19 - 1045:21	Prevoznik, Thomas 05-17-2019 (00:00:03)	TP01.448
	1045:19 QUESTIONS BY MS. SINGER: 1045:20 Q. -- and say, "We only use that 1045:21 data for marketing" --	
1045:23 - 1046:01	Prevoznik, Thomas 05-17-2019 (00:00:04)	TP01.449
	1045:23 QUESTIONS BY MS. SINGER: 1045:24 Q. -- "or accounting." 1045:25 You have to use that data for 1046:1 compliance, too, correct?	
1046:03 - 1046:03	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.450
	1046:3 THE WITNESS: Yes.	
1051:09 - 1051:14	Prevoznik, Thomas 05-17-2019 (00:00:11)	TP01.451
	1051:9 Q. In that last sentence that 1051:10 "chain store due diligence reviews must not 1051:11 be treated any differently than independent 1051:12 retail pharmacy customers," does that 1051:13 represent the view of the DEA? 1051:14 A. Yes.	
1052:05 - 1052:07	Prevoznik, Thomas 05-17-2019 (00:00:03)	TP01.452
	1052:5 That's the guidance that DEA	

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	1052:6 gave to registrants? 1052:7 A. Correct.	
1052:08 - 1052:11	Prevoznik, Thomas 05-17-2019 (00:00:15)	TP01.453
	1052:8 Q. All right. Should distributors 1052:9 be looking at all of the volume of opioids 1052:10 they supply into a geographic area in 1052:11 determining whether orders may be suspicious?	
1052:15 - 1052:22	Prevoznik, Thomas 05-17-2019 (00:00:11)	TP01.454
	1052:15 THE WITNESS: It would 1052:16 definitely help. 1052:17 QUESTIONS BY MS. SINGER: 1052:18 Q. Okay. Meaning if they're 1052:19 supplying in ways that are very 1052:20 disproportionate to the population, that 1052:21 should be a sign that they're not supplying 1052:22 to a legitimate market, correct?	
1052:25 - 1053:05	Prevoznik, Thomas 05-17-2019 (00:00:07)	TP01.455
	1052:25 THE WITNESS: Correct. 1053:1 QUESTIONS BY MS. SINGER: 1053:2 Q. And distributors may not know 1053:3 all of the pills that are going into an area, 1053:4 but they certainly know what pills they're 1053:5 sending, correct?	
1053:11 - 1053:11	Prevoznik, Thomas 05-17-2019 (00:00:01)	TP01.456
	1053:11 THE WITNESS: Correct.	
1054:16 - 1054:23	Prevoznik, Thomas 05-17-2019 (00:00:21)	TP01.457
	1054:16 Q. Let me do it as an 1054:17 example. 1054:18 If the threshold says that an 1054:19 order of 10,000 dosage units exceeds 1054:20 threshold and a customer orders 50,000 dosage 1054:21 units, can the distributor just cut the order 1054:22 to 10,000 units and ship it without 1054:23 investigating whether it's suspicious or not?	
1055:02 - 1055:12	Prevoznik, Thomas 05-17-2019 (00:00:19)	TP01.458
	1055:2 THE WITNESS: Well, in your 1055:3 hypothetical it sounded like it was 1055:4 already triggered as a suspicious 1055:5 order, so immediately upon discovery 1055:6 they were supposed to tell us anyway	

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	1055:7 that this happened. 1055:8 QUESTIONS BY MS. SINGER: 1055:9 Q. And shipping less of it doesn't 1055:10 make it not suspicious anymore. If it's a 1055:11 suspicious order, it's a suspicious order, 1055:12 correct?	
1055:15 - 1055:19	Prevoznik, Thomas 05-17-2019 (00:00:09)	TP01.459
	1055:15 THE WITNESS: Right. So they 1055:16 can either not ship it or they can 1055:17 investigate to determine -- to 1055:18 alleviate the suspicions that they 1055:19 have.	
1056:19 - 1056:24	Prevoznik, Thomas 05-17-2019 (00:00:14)	TP01.460
	1056:19 Under the title "Ensuring 1056:20 Patient Access and Effective Drug Enforcement 1056:21 Act," first sentence, "The United States is 1056:22 currently facing an opioid epidemic." 1056:23 Is that the view of the DEA? 1056:24 A. Yes.	
1262:07 - 1262:09	Prevoznik, Thomas 05-17-2019 (00:00:05)	TP01.461
	1262:7 Q. Okay. You didn't want to sit 1262:8 down with HDMA to help the public? 1262:9 A. No.	
1262:13 - 1263:03	Prevoznik, Thomas 05-17-2019 (00:00:30)	TP01.462
	1262:13 THE WITNESS: No, we sat 1262:14 with -- we did the distributor 1262:15 initiative because of what we saw, and 1262:16 we saw that the registrants needed to 1262:17 be -- have -- to sit down with the 1262:18 registrants, talk to them and go over 1262:19 their own data with them to show the 1262:20 anomalies that are going on, in the 1262:21 hope that they would stop what they 1262:22 were doing. 1262:23 They said they were going to 1262:24 fix it; they didn't fix it. So we 1262:25 weren't going to go to a trade 1263:1 association if the registrant isn't 1263:2 going to fix their own internal system 1263:3 that they have.	

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Defense Completeness Counters = 00:02:38

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